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Barriers to medical error reporting and disclosure by doctors: a bioethical evaluation

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Barriers to medical error reporting and disclosure by doctors: A bioethical evaluation

Trevor Robin Carmichael

A Research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Bioethics and Health Law.

Johannesburg, 2017

Declaration

I, Trevor Robin Carmichael, declare that this Research Report is my own work. It is being submitted in partial fulfilment of the requirements for the degree of MSc (Bioethics and Heath Law) at the University of the Witwatersrand, Johannesburg. It has not been previously submitted for any degree or examination at this or any other University.



Trevor Robin Carmichael

19 June 2017

Dedication

This research report is dedicated to my wife and family as well as my colleagues who have supported me throughout all my endeavours.

Acknowledgement

To my supervisors, Professor Ames Dhai and Dr Kevin Behrens, for their time, effort, skill and advice. Thanks you for helping me to complete this research.

Research outcomes

The research results will be made available to doctors who completed the questionnaire following publication.

The research will be reported at a National congress – the Ophthalmological Society of South Africa Congress in Port Elizabeth in March 2017.

It will be reported at the World Congress of Bioethics, Medical Ethics and Health Law, Cyprus - March 2017

The work will be submitted to an appropriate journal such as the South African Medical Journal or the South African Journal of Bioethics and Law.

A benchmark to guide doctors will be developed and proposed to the HPCSA for possible inclusion in its ethics guideline documents.

Abstract

Medical errors that occur in public sector hospitals should be discussed with patients and notified to specific structures to improve systems and patient safety. To elucidate barriers to doctors reporting errors and to establish correct ethical requirements, a mixed methods approach was used. A normative literature-based analysis was done to determine the correct ethical processes taking into account South African legislation. In addition a questionnaire-based internet survey (using REDCap) was conducted at the School of Clinical Medicine (SOCM) at the University of the Witwatersrand which examined the current situation and attitudes towards medical error disclosure.

There were 211 clinicians who completed the survey. Public sector hospital staff shortages and patient overloads (96%) as well as poor record-keeping systems (89%) were identified as important reasons for errors. Fears of victimization by colleagues (59%) and medico-legal consequence (56%) were prominent as reasons not to disclose medical errors. Poor reporting systems available to doctors (66%) and insufficient support from senior staff made it difficult for doctors to report errors. Training on correct disclosing of errors to patients and family was seen as necessary to improve skills and facilitate effective disclosure (94%). There was general agreement that doctors 'ought to' disclose harmful medical errors (83%) and to a lesser degree 'potentially harmful' errors to patients (70%).

Ethical guidelines that are appropriate for South Africa are suggested, as well as the introduction of easier reporting systems. For disclosure, a safe environment that protects against victimization and medico-legal prosecution is important and legislation to support this is urgently required. Training for doctors in correct methods for adequate disclosure and apology will assist improving patient care.

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Preface

The physician can bury his mistakes, but the architect can only advise his client to plant vines (to cover the ugly buildings with Ivy).

American architect Frank Lloyd Wright (1931)[1]

This project started to investigate why doctors are unwilling to report medical errors in Public Sector hospitals. This followed an analysis of an error-reporting system I established in the Department of Ophthalmology in 2011. Having worked under Dr HGV Kustner, Epidemiologist in the Department of Health 1980 to 1981 analysing the country's 'Notifications of Communicable diseases' data, I had some insight into notification systems and the problems of underreporting. The South African National Department of Health (DoH) introduced national core standards during the period 2009-2011 encouraging the use of Morbidity and Mortality meetings to gather data and improve governance and patient safety.

In Ophthalmology, I introduced a notification sheet and specified adverse events or outcomes that would serve as alerts to system failures as well as requesting notifications of specific problems such as operating theatre disruptions due to air conditioner failures. I analysed the first three years (2011-2014) and reported the results at our national ophthalmology (OSSA) congress. When comparing the notifications of endophthalmitis received over the period with actual cases taken to theatre over the period, the notification rate was estimated to be only about 20% of cases that occurred on the circuit. Having explained carefully and repetitively the importance of reporting cases, the doctors continued to underreport events and in some instances doctors were found to hide errors and complications during their training. The current research was planned to establish the barriers to medical error reporting and examine ethical imperatives for doctors to comply with such a request and the study was extended to the entire School of Clinical Medicine (SOCM) in the Faculty of Health Sciences

Chapter 1 Literature review, general methods and research design

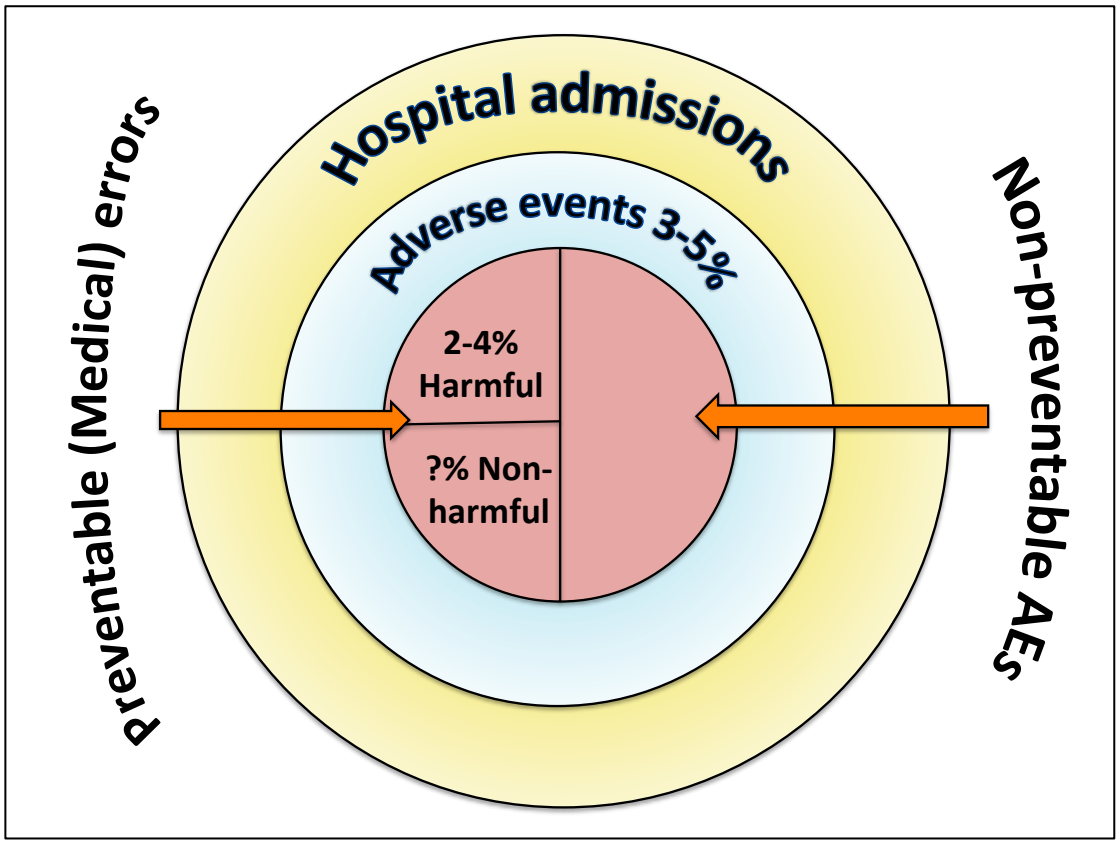
1.1 Introduction

This chapter will present a literature review of the barriers to medical error reporting locally and worldwide. This will be followed by the methods for the the research project as were contained in the approved protocol. It will end with an overview of the remaining chapters. Further detail on the methods used for the questionnaire-based survey will be further discussed in chapter three, following the normative analysis (chapter 2) and preceding the questionnaire results which are given in chapter 4.

1.2 Literature review

Worldwide appreciation of the importance of medical errors, either personal or system errors, has increased since the Institute of Medicine (IOM) report on Health Quality in American hospitals appeared in 2000.[2] In this report medical errors were defined as an injury to the patient caused by "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."[2] Of hospital admissions, adverse events occur in a percentage of patients, half of which are preventable (medical errors). The data show that about 3-5% of hospital admissions in the USA suffer 'adverse events' and at least half of these are preventable (medical errors).[3,4] The number of near miss (non-harmful) medical errors is not known. For harmful errors, an accepted figure is near 4% of patients who had disability, death or a prolonged hospital admission because of medical error by a doctor or the health system.[5] Medical errors are, by definition, preventable so do not include adverse events that are not preventable. To illustrate this I have represented this relationship graphically (see Figure 1.1).

Figure 1.1 Total hospital admissions, adverse events and preventable adverse events (medical errors)



Medical errors can occur during all stages of treatment or diagnosis of patients. Patient safety is the obverse, "freedom from accidental injury".[2] Medical errors were reported as having killed up to 98 000 patients per year in North America, more than motor vehicle accidents, breast cancer or AIDS.[2] A recent report called for medical errors to be listed as a cause of death on death certificates because it's the third leading cause of death in the USA after heart disease and cancer.[6] Although the IOM report dwelt on systemic errors, about half of the errors were due to doctor faults, including poor planning, "skill-based lapses" or "knowledge-based" errors.

This is not a new phenomenon and mistreatment has probably been around as long as medical treatment has been available[5] but the opportunities for error have increased along with the increasing complexity of medical care. In

complex systems, such as the healthcare system, many barriers may be created to prevent injury to patients for each step in the process of delivering the end result. The more complex each step becomes, the more chance that weaknesses occur and eventual damage to patients may occur. An analogy or model may be used to describe this. Models have been described as "a systematic representation of a knowledge domain, that is, a series of related concepts and the particular relationships across these concepts".[7] The analogy of layers of Swiss cheese has been used to explain the concept in medical errors occurring during health care. In the "Swiss cheese model", holes in adjacent slices of cheese can eventually line up creating a brief window during which harm occurs to patients.[8] The more complex the systems are, the more holes (weaknesses) appear, and eventually patient injury may result. The analogy or metaphor is not understood in exactly the same way by health safety experts[8] but does help to explain why adverse incidents have become so commonplace with medical advances.

In ancient times, shamans and witchdoctors called on ancient spirits and ancestors for healing power. These practices still exist in some areas but have largely been replaced by evidence proven scientific-based medicine with all its impersonal cold scientific precision. Whereas early errors may have been seen as “a sign from God”, for the last few decades medical and other errors within the system have been poorly tolerated and patient expectations are increasingly those of perfection.[5] One of the earliest disclosures of medical errors in 1984 stated “Our profession is difficult enough without having to wear the yoke of perfection.”[9] This early report of one doctor’s failures was greeted by censure from many colleagues but was the first call for a new approach to medical errors in medicine. In 1997, before the IOM report, the ethics of disclosure were lucidly described and discussed and obligations of doctors well understood.[10] Undoubtedly we may be partially at fault for teaching junior doctors that they have entered a ‘zero tolerance profession'. Doctors have been shown to to under-report errors and 43% were found to be willing to conceal a medical error if they could avoid punishment.[11] Positive role models have been reported to be important in training junior

doctors but negative role models are even more impactful in entrenching a culture of 'burying errors'.[12]

There are several levels to medical error reporting. Simple notification of the problem, which might even happen anonymously, or full disclosure including an admission that the error was made by the doctor her/himself, and then a further level, offering a sincere apology to the patient for the injury. According to Robbennolt, apologies alone can be a powerful balm for both the patient and the doctor and should be offered by the doctor where harmful errors have occurred.[13] The problem in doing what might seem obvious is that it may be unclear initially what all the factors involved in the adverse event were and who was to blame, if anyone. In this scenario Robbennolt suggests it is best to "express regret and sympathy along with the assurance that an investigation will take place".[13] This will then require follow-up communication and perhaps a further specific apology. The sensitive issue of apologies will be discussed further in Chapter 2.2.2 below.

Ethical standards required are underpinned by the principles of patient autonomy, beneficence and non-maleficence to which each graduating doctors swears allegiance and place the patient's wellbeing above that of their own. The American Medical Association (AMA) ethical guidelines (Code of Ethics: Opinion 8.12) entrench honesty in the doctor-patient relationship "It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients".[14] This is similar to the Health Professions Council of South Africa's (HPCSA) ethical guidance to practitioners in the country.[15] The AMA states that in the event of medical error "the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care".[14] The HPCSA, on the other hand is silent on this issue. The AMA make it clear (Code of Ethics: Opinion 10.015) that "The relationship between patient and physician is based on trust and gives rise to physicians ethical obligations to place patients welfare above their own self-interest….".[14] There are, however, some valid concerns by doctors about each level of error disclosure. The

barriers preventing disclosure of errors are real and fifty years ago the doctor could perhaps hide behind a shroud of medical jargon and mystique in a world that patients revered. Increasingly patients can access information and become more knowledgeable on their own disease than their doctor, using ‘Dr Google’ as a quick and cheap opinion. The Medline database became available to the public in June 1997 during President Bill Clinton's term of office. The use of PubMed for easy and often free access to medical literature was responsible for some of this when 'PubMed', a database of most reputable medical publications was made freely available to humanity.[16]

One of the most obvious and real barriers to disclosure is the fear of litigation[13] but loss of status and denial of our own errors are perhaps as important. Self-confidence of doctors can be fragile and making a serious medical error may cause emotional distress to sensitive and caring physicians, exactly the type we would like to see in practice.[17] Sometimes the error is multi-factorial and doctors choose to put a 'spin' onto the explanation so they don't appear to be the main or only reason for the error. The result of patients wanting full disclosure and full apology and the need for doctors to protect themselves can lead to eventual dissatisfaction on both sides. Keeping a “cautious tongue” was advice given to doctors back in the 1930's.[18] The medical profession has not found an answer to the cycle of medico-legal threats and reactionary defensive medical practice, rising insurance costs and increasing costs of medical care in this environment. Some claims are misguided and reflect poor communication which can be addressed, with appropriate intervention, an apology, and without litigation.[19]

As higher expectations drive medical progress the bar is continually raised. In South Africa, the expectations are often that first world medical care can be delivered within the public sector healthcare system. In some situations it can be, but glaring holes sometimes appear within the system making it ludicrously simple for lawyers to milk the Provincial coffers without much opposition. Individual negligence by doctors is one thing but to guarantee ‘patient safety’ in the public sector hospitals is becoming increasingly difficult. In this environment doctors are seemingly more likely to ‘blame the system’

and the constant shortages rather than take personal responsibility even if they are at fault. The lack of personal repercussions makes them somewhat immune to persecution and feeds their belief that they are above reproach. Doctors rightly fear medical litigation and settlements against them. The amount of settlements awarded in individual cases has increased dramatically and the number is also rising which is beginning to threaten the existence of some areas of practice such as obstetrics and neurosurgery.[20]

Doctors might have to face up to changes in the way they handle errors. It might help to create a national litigation authority/council to arbitrate cases in place of litigation.[20] The South African Medical Protection Society offers some guidance to doctors " Try to be sympathetic and understanding. Offer condolences if these are due. Do not be afraid of apologising if an error has been made".[21] The patient's views are that they want an acknowledgement and detailed explanation of errors and an apology for their injury.[18] The problem is, as Archbishop Emeritus Desmond Tutu says, "If you take my pen and say you are sorry, but don't give me the pen back, nothing has happened".[13] To avoid litigation and pay-outs, showing compassion and on-going patient care plus involvement of early second opinions from colleagues can assist.[22] These should be done without the threats of litigations to create a safer environment to enable doctors to do this.

New approaches worldwide have seen 'no fault' resolutions carried out where disclosure and settlement is agreed but it is capped.[5] This prevents outrageous and crippling awards in cases that would not seem to warrant it while many poor people with serious issues who cannot afford on-going legal battles are deprived. In South Africa the law deals with claims according to 'the common law', and more specifically the law of delict where negligence is determined by the criteria of "reasonableness and foreseeability".[20] The legal aspects are further discussed in chapter 2.

Doctors' obligations to patients are to help them and ease their suffering and not to unnecessarily unburden themselves of their own anxieties and insecurities by transferring this to the patient. This makes decisions relating to

disclosure sometimes quite complex and we expect doctors to manage this with sensitivity and appropriateness but sometimes without specific training in these areas. Doctors might require more training or protection from the litigation that they fear. Bioethicists may assist by guiding doctors to disclose certain errors and not others. Some errors are clear-cut and irrefutable such as removing the wrong limb. In this case most doctors would support disclosure but other areas are less clear-cut and easier to hide, such as adverse drug reactions[23] or diagnostic errors. Defining appropriate levels of disclosure is where the challenge lies.

1.3 Methods and research design

1.3.1 Research Question

What are the barriers to South African doctors notifying and disclosing medical errors and what would be the best ethical way for them to address these issues in South Africa?

1.3.2 Rationale

Claims against the Department of Health in South Africa (DoH) had reached over R10 billion by 2015 and indications were that this was an increasing problem.[24]

Governance systems within Public Sector Hospitals were seen to be suboptimal and the DoH introduced several measures aimed at improving safe care delivery in the Public Sector. The 2009 Strategic plan made Medical & Mortality (M & M) meetings compulsory for Public Sector doctors so that errors could be examined and medical systems and practices improved and in 2011 National Core Standards were introduced.[25] The Core Standards set levels which could be expected within the public sector, perhaps with an eye on the looming National Health Insurance (NHI) which had been long in planning stages. In spite of these pro-active moves, a Medico-legal summit in

March 2015 focused on the epidemic of claims against the DoH and explored reasons for this.[20] A recent (2016) document on patient safety by the Department of Health, South Africa, details and entrenches new patient safety procedures and also the procedures for notification of 'Patient Safety Incidents' (PSI). The document introduces an element of urgency so that notification for deaths etc. needs to be within 24 hours with an immediate investigation and discussion with patient and family and apology if indicated.[26] In the Department of Ophthalmology, University of the Witwatersrand (Wits), under-reporting of specified adverse events during M & M meetings has been noted. This was estimated at only about 20% of serious medical events being reported In spite of reminders to notify errors as well as serious complications. The current study examines why doctors are unwilling to report errors and also considers what the correct ethical and moral action should be, given our situation in the southern part of Africa.

1.3.3 Hypothesis

There exist some real or perceived barriers to acknowledging medical errors, which doctors ought to report, and these barriers are in conflict with the doctor's obligations of non-maleficence and beneficence.

1.3.4 Aims

To investigate the barriers to doctors reporting, acknowledging, and remedying medical errors, and to explore the ethically correct way for them to manage the situation should it arise.

1.3.5 Objectives

1.3.5.1 Primary objective

To determine actual barriers to reporting of medical errors in South Africa.

1.3.5.2 Secondary objectives

a) To describe and defend the bioethical position with respect to how doctors 'ought to behave' (normative behaviour) bearing in mind the medicolegal and other consequences of doing so. This will include evaluation of existing laws with respect to error disclosure and protection for doctors and contrast those in South Africa with those in other countries.
b) To stratify the results to establish differences in attitudes with gender, specialty (medical or surgical) and with years of experience.

1.3.6 Research design and methods[27]

The study design employed a mixed methods approach with both normative and descriptive/empirical components.

The normative component sets out to analyze and answer what ought to be done when a medical error is encountered in practice in a systematic, critical manner and to justify the answers that are offered. This component uses ethical theories and principles to critique relevant literature and considers the correct practical way forward, given our constraints in South Africa.

The empirical component, by use of a quantitative, structured questionnaire explored the 'lay of the land' and examined what is actually being done currently, in order to describe the facts that are relevant to the normative enquiry. The empirical component can be described as the 'descriptive ethics' aspect of this study and is cross-sectional and questionnaire-based. This part of the study consists of a questionnaire that was sent out to 1 546 doctors in the School of Clinical Medicine of the Faculty of Health Sciences (SOCM) looking at barriers to disclosing medical errors. After the analyses of the statements the results were compared with the normative position. This approach is similar to that described by Kon[28] which defines a role for empirical research in bioethics. As Kon describes, a "lay of the land" study is performed to establish the status quo and this can be followed by an 'ideal versus reality" level where the empirical data are compared with the normative expectations.[28]

1.3.7 Ethics and ethics clearance

As this was an on-line survey, signed informed consent was not requested. Response to the survey was presumed to imply tacit consent, however a comprehensive information sheet accompanied the email survey (see appendix 2). The confidentiality of questionnaires and recipients was assured by the removal of responder identifiers and the system of data collection (REDCap) used.

Approval of the research was obtained from the Human Research Ethics Committee Medical (HREC) of the University of the Witwatersand, before proceeding. Unconditional approval was obtained on 5 August 2016: Clearance certificate number M 160516 (see appendix 3).

A plagiarism declaration by the author is attached (see appendix 4).

1.4 Overview of chapters

Chapter 1

This chapter uses literature review to describe the punitive environment in South Africa with medico-legal claims escalating and threatening some sectors of medical practice. The phenomenon of patient injury by medical error has become increasingly recognized worldwide and new strategies need to be planned to increase patient safety. The chapter described the basic methodology and design used in the current research report. This research was double-edged, with a normative analysis to establish the gold standard for medical error disclosure followed by a quantitative questionnaire-based study performed to obtain facts about the current situation within the SOCM. Further methodology detail pertaining to the quantitative part will be presented in chapter 3.

Chapter 2

In this chapter the legal framework and the main moral theories appropriate to medical errors are examined. An argument to support open disclosure of

errors is presented and apologies to patients for injury is considered. The imperative to disclose medical errors in public sector hospitals is now a reality with a recent directive on the issue by the DoH. This normative assessment establishes a gold standard for disclosure of medical errors.

Chapter 3

Some further methodology that was used specifically in the quantitative research component (questionnaire) is presented. This chapter also contains a comparison between the School of Clinical Medicine (SOCM) doctors and the doctors who responded to the email survey (the responders). This is presented to try to establish systematic differences, such as the gender proportions, to have a way of assessing non-response bias. Response rates are also discussed in this chapter.

Chapter 4

The results of the 24 items (statements) from the 'lay of the land' survey are given with a statistical analysis of each. There is a brief discussion of the item results but the main discussion of the results is presented in chapter 5.

Chapter 5

The chapter begins with a brief discussion of the demographics and response rates from the SOCM study. The remainder of the chapter focuses on specific barriers to medical error reporting that were found to exist in the SOCM. These are considered under headings that group several items where they have a common theme (the barriers to disclosure). These seven barriers were compared with what has been found in the literature and also considers the major problem areas within the SOCM. The chapter ends with a discussion of the prima facie obligation to disclose and how it may at times conflict with doctors' responsibilities to maintain the medical care system in order to provide patient care to the entire public sector population.

Chapter 6

Conclusions and recommendations are presented and these include some specific suggestions for improving the notification of medical errors.

Chapter 2 Proper disclosure of medical errors in South Africa

2.1 Introduction

In this chapter I will argue that open transparency is the gold standard and disclosure of all medical errors ought to be made. An apology to patients' for injury is also expected. I will begin by examining the legal obligations for disclosure of errors and then the support provided by relevant ethical and moral theories as well as professional standards relating to medical errors.

Medical errors are of two general types.[29] System errors in which adverse events including preventable errors occur because of poor hospital or clinic systems. This includes unavailability of medical records, medication not available or poorly maintained equipment. Individual errors are a failure of health personnel to perform something that is expected, such as a proper examination of a patient, or something that is improperly and negligently done, such as performing the wrong operation or keeping illegible notes, which result in injury to a patient.

2.2 Law relating to disclosure of medical errors in South Africa

South African law contains many general as well as more specific protections for patients. Rights of patients are entrenched within the South African Constitution (SAC) and the Patients' Rights Charter (PRC).[30] Beneficence and the duty of doctors to help those in need, is also contained in the 'International Bill of Rights' and 'African Charter'. This protects the autonomy of patients which is their right to decide on what treatment is initially given as well as their subsequent management.[31] Patients cannot make a proper decision unless they are informed as to their individual progress and importantly any complications of treatment that require decisions. Non-maleficence, the obligation for doctors to ‘do no harm’, is similarly entrenched in these key documents.[31] This obliges the doctor to "minimize harm" to patients and

implicit in this is disclosure of errors to patients as this information is relevant to prevent further harm or injury.[29] In terms of disclosure of medical errors to patients specifically, there is not much but our SAC protects “bodily integrity and psychological integrity”. Since these are considered to cover informed consent, disclosure of injury due to medical errors that a patient has sustained may be assumed to be included under this protection. The patient's right to confidentiality must also be protected and disclosure of specific details of patients who have sustained injury has to similarly be carefully protected. This needs to be considered with regard to medical reports of injury that are sent by email and other non-secure methods. It is implied that harmful medical errors should be disclosed to patients as our SAC and PRC protect the rights of patients to “courtesy and human dignity”.[31] The National Health Act does not specify medical errors but Chapter 2 Section 6 makes it clear that a patient needs to be fully informed about the choices of treatment available and associated risks and in section 7 must give informed consent "for the provision of a specified health service".[32] This suggests that where a harmful error has occurred the proposed way forward needs to be discussed. Similarly the General Ethical Guidelines for the Health Care Professions (Booklet 1)[15] protects the patient with informed consent (section 5.3) and also participation in the decisions regarding their management (section 5.5). This again is mostly of relevance with respect to harmful errors. Although the SAC does allow for limitations to rights in Chapter 2 section 36, these need to be carefully considered and specifically motivated and applied very carefully. In this regard, "the importance of the purpose of the limitation" and "the nature and extent of the limitation" should be considered to see if there is lesser way to solve the problem than removal of rights.[33]

Although much of the legislation is directed toward 'harmful' medical errors, the protections in terms of 'courtesy and human dignity' go beyond this. In South Africa the National Health Act (NHA) Chapter 3 section 21 provides for National Health Services to be established and this implies that the National Department of Health (DoH) might in turn direct doctors (sometimes via Provincial Hospital Authorities) to perform certain obligatory functions or duties.[32] If they request medical error notification, doctors working within the

Public Sector who are broadly speaking their employees, will need to comply with this. For public sector doctors the requirement is now for mandatory reporting of adverse events (called PSIs or Patient Safety Incidents) in hospitals (and other public sector health facilities such as clinics) and this forms part of a new policy document from the DoH, which was made available in the second half of 2016. Mandatory requirements are nothing new. There is existing legislation in South Africa which is mentioned in the DoH document,[26] for mandatory notification of births and deaths, specifically procedure-related deaths, adverse drug reactions where registered drugs are used, blood transfusion reactions where these are "serious or life-threatening", and there are also over 30 severe epidemic diseases for which mandatory notification is a requirement.[34] All of these mandatory requirements involve birth, death or severe events and none is a 'near miss' or non-event. This document was originally developed by Leape, an expert on medical errors,[35] and has been modified and improved since 2005 by the WHO and is now being piloted globally.[36] The PSIs to be reported range from death or serious harm (Severity Assessment Code [SAC] 1) to 'near miss' events where no harm occurred.[26] Although doctors should report events as directed it is recognized in section 5.8.1.1 that only 10-20% of errors are reported by health care personnel and file review would need to be conducted to find every instance of error even if doctors write them down in the patient notes. Since SAC 1 events need to be notified within 24 hours, it seems sensible to perhaps focus initially on setting up a system to rapidly detect major problems and try to refine it later to include non-harmful 'near miss' episodes (part of SAC 3) unless they have major learning potential. SAC 2 events are moderate harm that might require medical or surgical intervention and/or prolong the hospital stay by between 72 hours and 7 days. The importance of feedback from the notification system to staff and patients is recognized in section 5.8.9.2 and this should include what has been changed and the improvements achieved. Information also needs to be conveyed to the patient along with "further expression of sympathy and, where necessary, regret that may include an apology with acknowledgement of responsibility for what has happened" as well as assurances of ongoing information. Doctors in private practice are not

bound by such obligations but are under the control of the regulating body, the HPCSA (Health Professions Council of South Africa).

Medical error reporting is intrinsically bound to disclosure of errors to patients that requires communication skills. Also related to medical error reporting are medical malpractice, negligence and the resolution of medical errors. Negligence and intention are to do with the nature of the error and who/what was responsible for it and are covered under South African Common law. Negligence and intention will need to be proven by the plaintiff on a balance of probabilities to win a case of negligence against medical personnel or hospitals. Medical error disclosure might indicate who or what was responsible and thus is related but is a separate issue. To have an open discussion of these elements requires freedom from the constant threat of litigation.[37] There is some legal protection for doctors in practice in South Africa as it has been established by case law that “medical mishaps” and “medical misadventures” sometimes occur during the intervention undertaken by the medical system and profession.[38] These, and also “errors of professional judgment” do not constitute medical negligence in South Africa.[38] The employer (the public sector hospital or Provincial authority) is vicariously liable for the actions of employees.[29,39] These situations will cover the usual and even unusual complications of medical and surgical treatment but where doctors are negligent the employer is not responsible. Medical negligence is where the doctor is found to have failed "to exercise the degree of skill and care of a reasonably skilled practitioner in their field of practice".[40] Medical malpractice may be deemed to have occurred where the doctor is seen to act intentionally and unlawfully.[40] Where an act of negligence has taken place and "reckless behavior" particularly where repeated episodes have occurred, disciplinary action by the employer might be considered.[26] The employer might also attempt recover costs from the doctor where possible.[39]

2.2.1 Resolution of medical errors

Disclosure of error is bound to a further discussion about compensation for the error and this needs to be correctly handled. According to Merry,[41] there

are three elements to the legal resolution of errors: Compensation, accountability (hopefully leading to better systems) and punitive action (against persons involved). In New Zealand, where a 'no fault' compensation system operates, there have been some concerns that the result might be a lack of responsibility for errors.[41] The South African DoH attempts to emphasize the learning opportunities from the disclosure of medical errors and therefore possible improvement to our operating systems in public sector hospitals.[26]

2.2.2 Specific legislation for medical error disclosure

Some countries or states (as in the USA) have legislation in place to enforce disclosure of medical errors.[42,43] although surprisingly, these differing laws for disclosure and apology within the USA do not always appear to convincingly affect the medicolegal claim rate.[44] In spite of laws offering protection, doctors might be unwilling to disclose errors and the legal profession have been accused of protecting doctors for "errors in judgment".[44] Lawyers have embraced the idea that medical practice is "an imperfect science". Apology protection legislation has been shown to be effective in some studies although in the USA there are differences in the protection offered.[45] Saitta reviewed the apology legislation in 36 states in the USA and concluded that it is becoming more widespread in the USA because patients prefer open communication to a "deny and defend" strategy.[45] The distinction "between a statement of sympathy and an admission of fault" is an important one. Saitta recommended, "if a physician's jurisdiction has the appropriate legislation, he or she should consider apologizing for an unexpected medical outcome". As we move from expectations of perfection and try to focus on safer systems,[46] apology legislation in South Africa might assist our doctors to use this strategy in cases where medical care causes preventable harm to a patient. Medical doctors might prefer to "self-regulate" their behavior rather than have systems imposed upon them but they are not the best judges of their colleagues.[47] Doctors often have a poor appreciation of medicolegal legislation and this has added to the perception that doctors prefer to remain silent, a questionable

tactic, with often has led to litigation by frustrated patients.[48] Peer review of colleagues performance has been used as a tool to improve patient safety[49] although the implementation may be problematic where specific complication cases are reviewed. The process of peer review began in the USA in the 1980's and became somewhat derailed by legal processes and competitive strife. It still retains value in retrospective file review of poor outcome areas or where a specific physician is getting sub-standard results.[49] It needs to be performed by unbiased colleagues to have validity.

It can be seen from the above that in South Africa, and other countries, there are general and somewhat specific protections for patients within the law and some usefully specific protections for doctors and health care providers. In South Africa we lack medical error disclosure legislation and apology legislation although the recent DoH publication[26] endorses these principles. Whether it is correct for the South African DoH to mandate that South African doctors disclose all errors without proper protection must be considered. Certainly doctors do not need to adhere to unreasonable requests or directives from their employer. "Doctors who refuse to carry out unprofessional, unethical or illegal directives from their superiors, or anyone else, may not be victimized by their actions".[39] In the USA, Clinton proposed changes in legislation be introduced to create a safer environment for medical error disclosure to ultimately improve patient safety and reduce costs (the MEDiC program).[37] In reality, changes in legislation may be slow to reach completion but the need exists for protective legislation to facilitate safe disclosure in South Africa.

2.3 The ethical path and principles for medical error disclosure

I will firstly define two importantly different areas for which the responsibility of doctors differs.

2.3.1 Two levels of medical error disclosure

Level 1 is the discussion the doctor might have with the patient and/or family. Level 2 is notification to some person or structure outside the immediate doctor/patient relationship. These two situations will be distinguished from each other during further discussion below.

2.3.2 Ethical principles that apply to medical error disclosure

There are three main moral theories that apply to disclosure of medical errors.[29] Utilitarianism, Deontology and Virtue ethics all have application in determining how doctors in South Africa should act.

Utilitarianism is a type of consequentialism where the consequences of the act determine its moral value.[29] If a good outcome results from the act then the act has moral value. Utilitarianism might also be considered in the light of the results from single acts (act utiliarianism) or where the outcome from predetermined rules are considered as to the overall positive or negative outcome from the rule (rule utilitarianism).[50]

The utilitarian approach is often applied in medical care of patients, as the 'best outcome' for each patient is the objective. Commonly this is a physical outcome of health improvement but it also includes the mental and emotional outcome. Making each patient happy is not usually the objective of medical management but is important. Specifically, in the disclosure of medical errors the best outcome is a patient who understands the changing issues in patient management and can assist in the decisions related to her/his future care. Disclosing medical errors may have immediate and delayed positive and/or negative consequences for both doctor and patient.[29] It will be assumed for the argument that the patient always ought to take priority over the doctor in terms of all decisions made where a patient is directly involved, and this is achievable in most situations. The law (as discussed above) favors this and is very clear that patient protections apply and the autonomy of the patient must be protected. This pertains to both initial management and also the ongoing

treatment including any “complications of treatment that require decisions”. Patients can expect competent treatment to be given. It is a requirement of all doctors that they do not begin a procedure unless qualified and properly trained to do it and it is a reasonable expectation by patients that this is provided.[51] This requirement was part of the "Ethical rules of conduct for practitioners registered under the Health Professions Act, 1974" in the Government Gazette Notice No. R 717 from 4 August 2006, which was included in the booklet.

The judgment about disclosure of errors to patients has traditionally been left to doctors in South Africa. The doctor would determine the safe and correct level of information conveyed to the patient as patients may differ considerably in their involvement in the treatment processes. The National DoH document released in the second half of 2016 makes all medical errors notifiable in the public sector institutions.[26] When this is implemented it similarly would be required that the patient or patients family was briefed as to the same situation that was considered necessary to notify, in other words, briefed as to the medical error that had occurred. This will change the dynamic and the decision to notify the patient therefore no longer resides with the doctor although the exact explanation and detail of the explanation still does. Rule utilitarianism would allow for some guidelines to achieve a common goal in reaching an acceptable outcome for most patients, satisfying the need for justice. These guidelines or expected norms might help to entrench open transparency in medical error disclosures and more open communication with patients. As part of this, harmful errors should be explained to the patient as has been part of the usual practice of medicine. Where a minor error occurs but with no harm to the patient and no management decisions are required this may be different and what is required for such near miss notifications is not as clear. Senior doctors directly supervise junior doctors who are learning their trade to minimize incidents and prevent errors and as a result, errors by juniors are often detected early, corrected, and this is how junior doctors are schooled in a safe environment. The training of new surgeons and surgical skills has a social utility that is well recognized. This process should be regarded as somewhat different from

near miss errors where a fault is discovered in a specific hospital system (or member of staff) that requires attention and correction.

The requirements of medical error disclosure also embrace the moral theory of Kant, referred to as Deontology. In Deontology, the rule replaces the 'best outcome' as being the determinant of correct action. This might sound similar to rule utilitarianism but the important difference is that deontology does not place merit in the outcome achieved by the rule. Correct rules determine correct action and the correct action has moral worth, not the outcome.[29] With respect to medical errors therefore, the situation is more clear-cut with less 'wiggle-room'. In spite of this, it is still not an easy matter to just 'follow the rules'. It remains the duty of the doctor to balance autonomy (patient's right to make choices), beneficence (assisting the patient), non-maleficence (avoiding harm) and justice (treating all patients fairly) and also managing conflicts that often occur between these obligations.[29]

Level 1 disclosure to patients is demanded by the doctor/patient fiduciary relationship which is built upon trust.[52] Doctors have clear obligations and imperatives regarding this responsibility and these should not be disputed. These duties go far beyond that which is legally required and have a moral force and value which follows on the special care and trust relationship that exist between doctor and patient and the obligations of deontology. The HPCSA guidelines spell out the obligations of doctors for ethical and professional practice and these need to be followed.[15] The American Medical Association (AMA) supports an obligation to inform the patient of medical errors “even though the patient’s medical treatment or therapeutic options may not be altered by the new information”.[3] This implies that even the most trivial error should be discussed with the patient. For level 2 disclosures in the South African context we have a National Health directive to disclose all errors that occur in public sector health facilities to learn and prevent repeat errors and detect faults. There is no direct legislation defining what should be notified but the DoH has been tasked with providing direction to the public sector healthcare system in the National Health Act of 2003.[32] If we are able

to disclose and notify medical errors, therefore, we should do so in all instances.

The moral theory of Virtue ethics takes a different view. The positive result obtained is reliant on a virtuous person who would be expected to act correctly.[29] It is not that they are following a set of rules (deontology) or trying to calculate how the best result can be obtained (utilitarianism) because by their character traits they should act in a way that will have the desired effect. We presuppose that doctors ought to have integrity and honesty.[29] This is the basis for the relationship that a patient presumes they hold with the doctor. A good doctor would seek out an understanding with each patient and serve his or her best interests without question.

In discussing the correct ethical way forward, in terms of error disclosure, certain general principles should be accommodated.[50] The argument for disclosure of medical errors must incorporate all three theories as discussed above but a starting point is deontological. Deontology suggests or requires a universal (categorical) obligation that is true for patient autonomy. The obligation to "treat every person as an end and never as a means only" is part of the way autonomy is ensured.[50] All patients require the same level of respect and protection and public sector patients who are probably a more vulnerable group will need even more consideration to assure adequate autonomy. They need to be given all the respect afforded to private healthcare patients and so ought to have the same levels of disclosure of medical errors, no more and no less. There might be conflicts in employing strict deontology in the workplace because a doctor, nurse or medical student might feel obliged to tell a patient what they know even where they are not the primary care physicians. This makes the role of the primary care physician very serious in ensuring medical errors are handled properly and patient autonomy is protected. Autonomy cannot be satisfied unless the patient can make free decisions with all relevant information available to them. Conflicting obligations to colleagues might arise while prioritizing patients and it is expected that doctors handle this correctly and with sensitivity.

Autonomy provides that patients have a prima facie claim to be informed.[50] This is not absolute but should always be the first consideration in a discussion of error disclosure. At times there are reasons why patients are not fully informed in spite of this claim. Rule utilitarianism may be used to justify non-disclosure under certain specific and defined circumstances because of lack of capacity in our healthcare system but cannot excuse non-disclosure. This might make allowances so that doctors can use their time and expertise correctly but is not the required norm.

An area of concern in South Africa is the unjust distribution of resources between public and private sectors. Doctors need to guard against the use of different standards for error disclosure between public and private sector. This already exists with the new policy document making all medical error notification mandatory in the public sector[26] but the private sector doctors are only bound by their interpretation of the HPCSA guideline documents[15,51] which do not specify medical error disclosure and reporting specifically.

2.4 Why doctors should disclose medical errors

Given the strong ethical principles and arguments why disclosure should be made, many authors argue for transparency.[5,12,35,36,43,53-56] Non-disclosure has been referred to as an “egregious violation of ethical principles” and the argument for disclosure includes many basic ethical principles.[57] A doctor's imperative to maintain patient trust is so fundamental to the practice of medicine that it is represented by the demands of Kant in fulfilling duty and obligations at all times.[29,53] The principles of utilitarianism are also directly pertinent because the practice of medicine is based on the special relationship between doctor and patient. Ultimately, to betray it could threaten not only personal reputation but also the whole standing of the medical profession in society.

For level 1 disclosure this determines the proper behavior of doctors. The guidelines of the HPCSA apply to this and direct what is correct behaviour.[15] There is a possible conflict between beneficence and autonomy and in seeking to help patients doctors need to guard against infringing patient

autonomy. Patient "autonomy and self-determination have been recognized as paramount".[40] Doctors want to help patients but have to guard against paternalism. Full autonomy is the expected due of mentally competent adults, and a suitable equivalent should be provided for children and mentally less capable where families can be brought in to assist in this situation. In this environment doctors would sensibly be dealing with the main issues and decisions surrounding the case and not minutia. Some patients are also not capable of rational decision by virtue of drug or alcohol abuse[50] and paternalism might be justified although family involvement in this situation is expected.

For the second level, where disclosure is made to some outside person/s or institution or structure, the same arguments mostly pertain. There is an imperative to notify as directed by the employer of public sector staff, as is seen with the recent DOH publication.[26] This enforces disclosure of 'all medical errors' including 'near misses'. In some hospital environments doctors might be directed to specifically notify only 'sentinel events' to encourage compliance rather than all events, harmful or not, which might be overwhelming. It has been clearly shown that doctors are most likely to notify 'harmful medical errors'.[18,58] Sentinel events are specific indicators of a problem, for example in Ophthalmology, post-operative endophthalmitis, a devastating eye infection, might indicate operating theatre standards have dropped. Other events might include operations performed on the wrong eye.[59]

2.5 Concluding comments

In order to improve systems and create safer hospitals information on errors is required. In discussing medical errors, the specifics of what the doctor may choose to tell the patient is to an extent situational, but the over-riding principal is for transparent openness.[10] The spirit of the recent booklet publication by the Department of Health, South Africa,[26] encourages openness. The argument in the above chapter supports the patient's legal and moral right to expect that doctors will always be honest and inform them of

any health issues and that includes mistakes or errors in their treatment. There are strong ethical demands for every patient to be as fully informed as possible and that every effort is made to improve medical care systems to improve safety in patient care.

The extent to which the SOCM doctors support the required open disclosure of medical errors and possible barriers to them doing so, were examined with a questionnaire survey and this will follow in the next two chapters. In chapter 3 further methods and preliminary analysis relating to the questionnaire are presented and the actual results from the questionnaire items follow in chapter 4.

Chapter 3 Methods used in questionnaire analysis and response rates obtained

3.1 Introduction

I will now consider the response rates of the questionnaire-based survey performed in the SOCM (School of Clinical Medicine). There were differences between the doctors who submitted responses to the questionnaire (which I will call the responders) and those who did not participate. How this was considered in the interpretation of the questionnaire results and the possible bias and confounding that could occur is described in this chapter.

3.2 Data collection and statistical analysis

REDCap (Research electonic data capture, Vanderbilt University) was used for the questionnaire survey. The system maintains confidentiality of responders and identifiers were removed to ensure this. The study was a cross-sectional questionnaire survey sent to the recipients by email (Appendices 1 and 2). Emails were sent on 13th September 2016 and over the subsequent four weeks three further reminder emails were sent with the final email sent on 11th October 2016. The study closed on 22nd October 2016 after no responses were obtained for one week.

3.3 SOCM survey clinicians

The SOCM is, in turn, part of a larger group of doctors who work as clinicians in the public sector hospitals in South Africa. In the SOCM study, non-response bias was addressed by examining available data for the entire School. Then a comparison of SOCM survey responders with the whole School was performed to see where there were obvious systematic differences in terms of gender, age etc.

The SOCM human resource data suggested that the SOCM contained 1 945 doctors where gender and position could be established and the profile could be compared to the doctors who completed the questionnaire.

Doctors included in the survey were medical doctors who were practicing clinicians (with available email addresses) on the University of the Witwatersrand public sector hospital teaching circuit: Charlotte Maxeke Johannesburg Academic Hospital (CMJ), Chris Hani Baragwanath Academic Hospital (CHB), Helen Joseph Hospital (HJ) and Raheema Moosa Mother and Child Hospital (RM).

Doctors excluded; were those who worked in purely research units, non-clinical departments and those for whom no email address was available.

Specialty (medical or surgical), gender and seniority were compared to establish if there were systematic differences between them. For this survey, medical (non-operating) specialties were Internal Medicine, Family Medicine, Neurology, Pediatrics, Radiation Sciences, Psychiatry and Anesthetics. Surgical specialties were General surgery, Obstetrics & Gynaecology, Neurosurgery, Otorhinolaryngology (ENT) and Ophthalmology.

3.4 Demographics

There were 211 responses obtained from 1 546 emails sent out. The overall response rate was thus 13.7%. The response rate differed by specialty and 57.5% (119) of the responses came from medical specialties while 42.5% (88) were from surgeons (of the 207 who specified their specialty). The response rate for surgeons was significantly higher than medical doctors 119 of 1 005 emails sent gave a response rate of 11.8% while 88 of 541 responded from surgeons which was 16.3% ($p=0.0148$ using a two sample test of proportions). The response rates in the strata (whole group, specialty, gender and seniority) will be further described below.

Cultural background within the 1 945 School clinicians was: 713 Black (36.6%), 704 White (36.2%), 477 Indian (24.5%), 42 Mixed Race (2.2%), and 9 Chinese (0.5%). The cultural background of responders was not sought and it will not be further considered.

There were some differences in the composition of the responders from the SOCM (see Table 3.1). Not all the items were answered by all of the doctors so the total number of responders differs for different items and also within the different strata.

Table 3.1: Gender and age differences between the SOCM doctors and the responders.

		Gender (n)		Male (%)	Age (years)			
	n	Female	Male		Mean	SD	Median	Range
SOCM	1945	999	946	48.6	40.34	9.9	38	25-87
Responders	211	116	76	39.6	40.65	11.7	36	25-82

Note: n is number, SD is standard deviation.

There was no difference in the mean age clinicians between the School (40 years) and that of the responders (4.7 years) where p=0.7114 (Two sample t test with unequal variance).

There was an over-representation of females in the responder group and this was significant. The proportion of males (39.6%) was significantly less than the proportions in the School (49%) where p=0.0166, Two sample test of proportions). This was considered a source of potential bias during the analysis.

For analysis, age groups were created to further compare the responders with the School (Table 3.2).

Table 3.2: Gender and age response rates to the questionnaire.

Numbers (%)	Gender		Age groups (Years)				
	Female	Male	25-34	35-44	45-54	55-64	65+
SOCM	999 (51.4)	946 (48.6)	678 (34.9)	763 (39.2)	298 (15.3)	160 (8.2)	46 (2.4)
Responders	116 (60.4)	76 (39.6)	87 (42.1)	64 (30.9)	21 (10.1)	28 (13.5)	7 (3.4)
Response rate	11.6%	8.0%	12.8%	8.4%	7.1%	17.5%	15.2%

Note: Numbers are used with percentages in brackets or specified as %.

Response rates for gender and age groups could be calculated where the doctors who responded gave the relevant information (gender was disclosed in 192 of the 211 responders and age by 207 of the 211 responders). The response rates were higher in the 25 to 34 year age group and lower in the middle age groups (35-54 years).

Significantly fewer males in the School responded and answered the questionnaire than women (p= 0.0005, two sample test of proportions). The response rate for males was lower for the 192 responders where gender was disclosed and was 8.0% compared with females who were 11.6%. this difference was significant (p= 0.0082, two sample test of proportions).

There were 181 South African born responders (86.2% of the 210 responders who shared this information). A further 18 were of African origin outside of South Africa (8.6%) whereas 11 (5.2%) were born outside Africa. The comparative proportions within the School could not be established.

The clinical experience of responders may be estimated in several ways and one indicator might be the position held at the time of the survey:
Work positions (n=206)
Junior posts (84): There were 13 medical officers (6.3%) and 71 registrars (34.5%) of the responders who provided this information.

Senior posts (122): There were 122 consultants (59.2%).

The problem with using this method of estimating seniority was that there might be some older registrars who might be more experienced than junior consultants. As year of graduation was requested, the duration of experience as a doctor could be established. Grouped years after graduation was used as a variable. Also a junior/senior variable was created where those who graduated in 2005 and after who were (arbitrarily) designated 'junior'. This meant that they had 10 years or less of work experience as a doctor. Those with more than 10 years experience as a doctor were designated 'senior'.

The year of graduation was requested and provided by 208 responders. The earliest graduate who responded had graduated in 1959 and the latest in 2014. The mean year was 2 000 and the median year was 2004.

Graduation groups by 10 year interval were created: Nearly half 101 (48.6%) were 'junior' having graduated in 2005 or after (Table 3.3).

Table 3.3: Graduation groups and gender by ten-year age interval

Year of graduation (n=208)	Number	Percentage	Gender (n=190)	
			Female (%)	Male (%)
1955-1964	2	1.0	0 (0.0)	2 (2.7)
1965-1974	5	2.4	1 (0.9)	4 (5.3)
1975-1984	27	13.0	6 (5.2)	18 (24.0)
1985-1994	19	9.1	10 (8.7)	7 (9.3)
1995-2004	54	26.0	33 (28.7)	17 (22.7)
2005-2014	101	48.5	65 (56.5)	27 (36.0)
Total	208	100.0	115 (100.0)	75 (100.0)

3.5 Reliability and response rates

(further discussion on response rates is in Chapter 5, section 5.2)

Response rates to questionnaires are typically low and can vary from 10 to over 50%. If 60% or greater response rate is obtained, non-response bias is not considered a problem but responses in clinician surveys in recent decades have declined.[60-63] In a study by Wiebe et al[60] there was only a 14% response rate and the authors explored this decline in response rate. There may be low precision if numbers of responses are less than 100 total. Responses might also differ by specialty.[64]

There are over 50 types of bias.[65] Biases, which are seen with survey questionnaires are 'non-response bias', where the doctors who do not respond may differ systematically from those who do. 'Recall' bias occurs where doctors might have poor recall of events that happened some time back. 'Hospital selected group' bias is possible in which doctors in public sector hospitals may differ from doctors in private practices who perhaps have more control of their environment. 'Social desirability bias' may result where no doctor wants to look as if she/he is hiding errors so might seek to 'impress the researcher' by his/her high standards. 'Acquiescence bias' is where statements (or items) are used in a questionnaire rather than questions and people are more likely to agree with a statement than disagree so the researcher could mould the response and results. Bias is due to errors in design of research the results are flawed. These errors might be lessened if a larger sample size is obtained. The use of internet surveys have advantages in terms of reaching a large number of doctors reasonably easier but may suffer from a lower response rate than other methods. The response rate may be of 11% lower for email questionnaires when compared with other modalities, telephone or postal surveys.[66]

3.6 Statistical Analysis

A statistician was consulted prior to starting the study. A small pilot study (seven) was performed to help refine the questions. It tested the time taken to complete the survey (5-10 minutes) and if the questions produce the desired

responses. The questions were then edited to produce the final version as in Appendix 1.

Data were collected into REDCap then imported into Stata 14 (Stata Corporation, College Station, Texas, USA) to do the final analysis which was performed by the author. For all analyses $p \leq 0.05$ was considered statistically significant.

The analysis of Likert questionnaire responses is contentious. The data collected from Likert scales are ordinal and in spite of this the use of parametric data analysis methods have been said to be appropriate and even more robust than non-parametric.[67] This infers that the usual arithmetic mean or better the median can be used for central tendency measurements and it is appropriate to use frequency tables and Chi square methods in the analysis. A proviso is that the data should at least have a 'near normal' distribution, sample size is adequate and that there are 5-10 observations per group.[67] The mean score obtained from Likert scales may not be meaningful, depending on the distribution. At least five Likert response categories are recommended as Likert originally suggested 5-7 categories.[67] The use of median (Kolmogorov-Smirnov test) and rank testing (Wilcoxon) or non-parametric testing (Mann-Whitney U test) can also be helpful, although it does depend on an initial evaluation of the actual values from the responses.[68] Essentially the results from the current research (the SOCM study) are expressed in tables showing medians and means with standard deviations and frequencies and proportions (%). Chi square testing was performed to establish significance for responses when examining the whole group for responses to each question, statement or item as required. This was done for for the different strata: Specialty (medical or surgical), gender and seniority. Summary statistics was done on the group as a whole and by stratification groups where indicated, as has been reported.[69] Where medians were different and means also appeared different, a t test was performed. Where a t test was used, a variance ratio test was performed first and the appropriate t test was used (t test for equal or non-equal variances). There are other

suggested methods for analysis of Likert scales including correspondence analysis[70] and distribution fitting[71] which were not explored in this study.

Multivariate analysis can be performed if over 100 responses are obtained. Logistic regression using a binary outcome as a dependent variable and testing either continuous or categorical data collected is robust and can be used if there are 20-50 responses for each independent variable.[72]

In addition to the usual variables of age, gender, specialty and seniority, transparency and non-transparency variables were created using a composite of questions that either favored disclosure or promoted hiding of errors. This was to establish if there were independent associations with this behavior pattern in the responses.

3.7 Sample size

This was determined from the literature and estimated to require at least 50-100 responses.[11]

The total number of doctors registered with HPCSA (Health Professions Council of South Africa) in 2015 was 42 323.[73] This also included those who were registered but overseas and retired doctors. The SOCM study was of 1 546 doctors which represents approximately 3.7% of the total doctors registered in South Africa.

A smaller sample size is permitted if the sample is over 5%.[74] Here the sample was 3.7% of all doctors registered and possibly over 5% if overseas and retired doctors were excluded from the HPCSA registered total. In a similar questionnaire-based study (paper-based) surveying surgeon's opinions on the Wits circuit, a response rate of 53% was obtained[75] but response rates to email questionnaires are often lower.

Purposive and convenience sampling was used in the SOCM survey. Purposive sampling involves sampling a specific group to address a specific

research question. In this research medical doctors had to be used to get informed information on various issues. The convenience sample differs from random sampling as random sampling allows each person the same probability of inclusion.[76] In convenience sampling this is not so and the mathematics and assumptions in doing analyses are thus different. It is statistically weaker but was the only available option to get adequate numbers of responses from doctors for the SOCM study.

3.8 Concluding comments

This chapter has shown that the response rate overall was 14% and was significantly better for surgeons (16%) than the clinicians from medical specialties (12%). Although there was no difference in mean age between all the clinicians in the SOCM and the responders to the questionnaire, possible gender bias exists as there was a significantly larger proportion of females (64%) in the responders than were present in the School overall (51%). Most of the responders were South African born (86%) and few were from outside of Africa showing that the survey group had knowledge of working conditions in South Africa.

The following chapter contains the results obtained from the questionnaire survey and brief statistical analysis of each item (statement).

Chapter 4 Results - The SOCM Questionnaire study

4.1 Introduction

This chapter contains the output from the SOCM questionnaire-based survey. There were 24 items (statements) and levels of agreement that were analyzed. The results obtained from each question with a summary analysis in a table for each question together with short comments. The methods used and population surveyed has been described above in chapter 1 and chapter 3 and the discussion of how the results compare with the normative requirements (chapter 2) will follow in chapter 5.

4.2 Barriers to medical error reporting: Results of questions

Each of the 24 items that follow is the response to the original 24-item questionnaire and information (appendix 1 and 2) sent to doctors via email link to REDCap. For each item (statement) a figure (bar chart) shows the number of responses obtained for each level of agreement. These were; strongly agree (score 5), agree (score 4), neutral (score 3), disagree (score 2) and strongly disagree (score 1). Following each figure is a table of summary statistics where mean (and standard deviation) and median scores were compared between the responses overall and various strata, specialty, gender and seniority. Where there were differences in mean or median statistical analysis was performed and the results included in the table. Where indicated, logistical regression was performed to check for confounding. A brief comment follows where there are differences but the discussion is mostly carried forward to the main discussion in chapter 5.

Item 1

'Medical errors by doctors' is one of the most important problems in health care today

Figure 4.1 Levels of agreement with item 1 (numbers of responses)

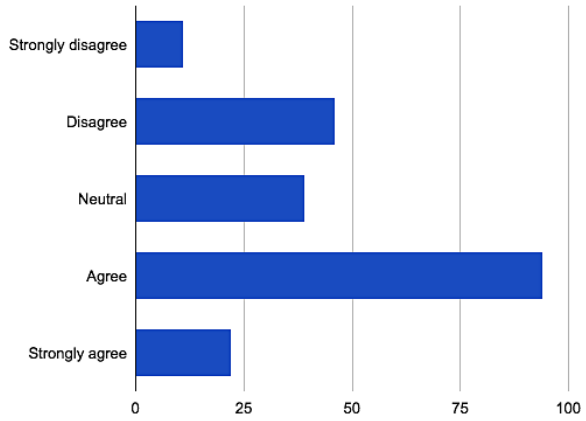


Table 4.1 Item 1: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 1	Answers for whole group (n=211)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	11	46	39	93	22	211
%	5.2	21.8	18.5	44.1	10.4	100
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	4	3.33	1.09		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	4	3.38	1.04		
Surgical	88	4	3.25	1.17	p= 0.4068*	
	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	4	3.29	1.00		
Male	76	4	3.26	1.24	p = 0.8599**	

	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	4	3.35	1.05		
Senior	107	4	3.31	1.14	p=0.8153 *	

Note:
S disagree is Strongly disagree

A median of 4 = Agree

* = t test for equal variance

** = t test for unequal variance

'Doctors making medical errors' was seen as an important current problem by 55% of respondents while 27% disagreed that it was an important problem. As there was a 'bimodal' response of agree and disagree, the results for the stratified levels were tested.

Comparing responses of medical versus surgical groups, there was no difference in variations so the t test for equal variance was used.
There was no significant difference in means between medical and surgical groups (p= 0.4068, t test for equal variance). For gender, variances were unequal and the test for unequal variances was used. There was no significant difference between means (p = 0.8599, t test with unequal variance). Comparing less experienced doctors with those who were more experienced (junior versus senior): There was no significant difference in means p = 0.8153 (t test with equal variance).

Comment: The median scores were the same for the stratified levels as in the whole group. The bimodal response overall with a mode at 4 (agree) and 2 (disagree), was due to slightly less agreement - could be seen in slightly lower mean scores - for surgeons of male gender who were senior.
Logistic regression was performed for the outcome 'agreement' with the statement that medical errors by doctors were an important problem. There was no independent association with medical/surgical groups, gender,

junior/senior or age that was significant either with or without controlling for the other variables.

Item 2

'Medical errors resulting from hospital errors/faults' is one of the most important problems in health care today

Figure 4.2 Levels of agreement with item 2 (numbers of responses)

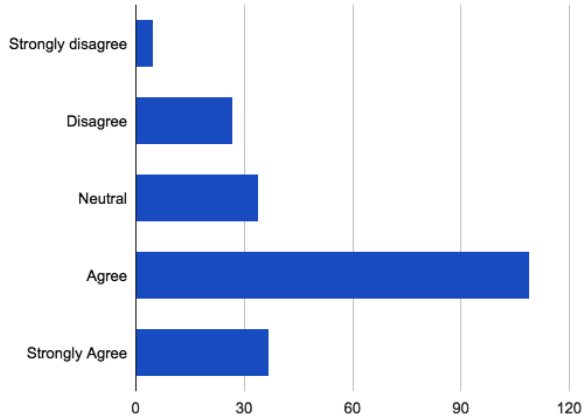


Table 4.2 Item 2: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 2	Answers for whole group (n=211)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	5	27	34	108	37	211
%	2.4	12.8	16.1	51.2	17.5	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	4	3.68	0.99		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	4	3.73	0.95		
Surgical	88	4	3.60	1.07		

	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	4	3.68	0.93		
Male	76	4	3.61	1.11		
	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	4	3.74	1.01		
Senior	107	4	3.62	0.99		

Note:

S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

The vast majority of doctors (68.7%) felt that medical errors from hospital faults and errors were one of the most important problems today but 15.2% did not think so.

For the stratified groups the results were similar to the whole group for medical or surgical specialty, gender or seniority according to year of graduation.

Item 3

There are easy to use systems for medical error reporting in my workplace

Figure 4.3 Levels of agreement with item 3 (numbers of responses)

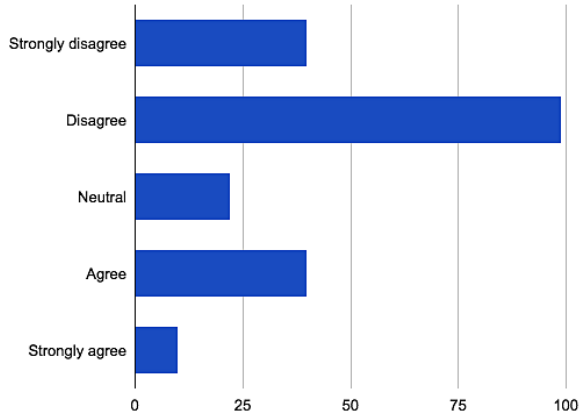


Table 4.3 Item 3 Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 3	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	39	99	22	40	10	210
%	18.6	47.1	10.5	19.0	4.8	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	210	2	2.45	1.14		
	Summary statistics for medical and surgical doctors (n=206)					
	Number	Median	Mean	SD		
Medical	118	2	2.41	1.18		
Surgical	88	2	2.51	1.19		
	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	2	2.47	1.18		
Male	76	2	2.45	1.09		

	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	2	2.40	1.14		
Senior	107	2	2.52	1.14	p= 0.4489	

Note:
S disagree is Strongly disagree

A median of 4 = Agree

* = t test for equal variance

** = t test for unequal variance

Most doctors (65.7%) do not consider the systems they have at work support the easy reporting of medical errors. There were 23.8% who appear to have easy systems in place at work.

On univariate analysis, tabulating variables against agreement with the statement, 24% of juniors thought there were easy systems but more seniors thought there were easy systems (31%) but this difference was not significant (Pearson Chi square p=0.310). The agreement between medical/surgical groups and gender were similar with no obvious differences. The medians were the same (2=disagree) and the means were not different in the strata.

There was a bimodal response although it was marginal so logistic regression was done to check which doctors had agreed and disagreed about the easy systems. A logistic regression model was created which included 169 observations with p=0.09, and regressed 'total agreement' (agree and strongly agree) with the statement that 'easy systems were in place' against explanatory variables medical/surgical group, age group and gender.
Agreement was more by seniors and older doctors where the 65 year and older stood out as significant on regression, when controlling for gender (p=0.01, odds ratio 20.3, CI 2.0-208.6). They and the older age groups (from 45 years and older) had a greater level of agreement. In the 45-54 age group it almost reached significance with p=0.086 and the odds ratio was 2.7 (CI

0.87-8.4). Males had an odds ratio of 0.54 (CI 2.0-208.6) - were half as likely to agree.

Item 4

Doctors should disclose all harmful medical errors to patients

Fig 4.4 Levels of agreement with item 4 (numbers of responses)

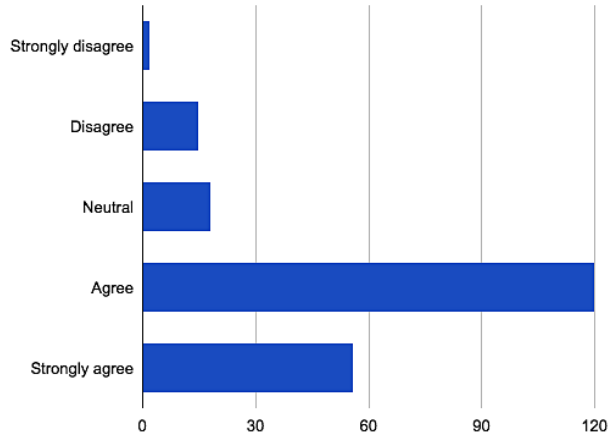


Table 4.4 Item 4: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 4	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	2	15	18	119	56	210
%	1.0	7.1	8.6	56.6	26.7	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	210	4	4.01	0.86		
	Summary statistics for medical and surgical doctors (n=206)					
	Number	Median	Mean	SD		
Medical	119	4	4.02	0.85		
Surgical	87	4	4.0	0.87		
	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	116	4	3.94	0.86		
Male	75	4	4.09	0.89		

	Summary statistics for junior and senior doctors (n=207)					
	Number	Median	Mean	SD		
Junior	101	4	4.04	0.73		
Senior	106	4	3.96	0.97		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

The vast majority (83.4%) of doctors believed that all harmful medical errors should be disclosed to patients, and only 8.1% disagreed.

The median answer was 'agree' and the means did not show much variation in the stratified levels.

Item 5

Doctors should disclose all potentially harmful medical errors to patients

Figure 4.5 Levels of agreement with item 5 (numbers of responses)

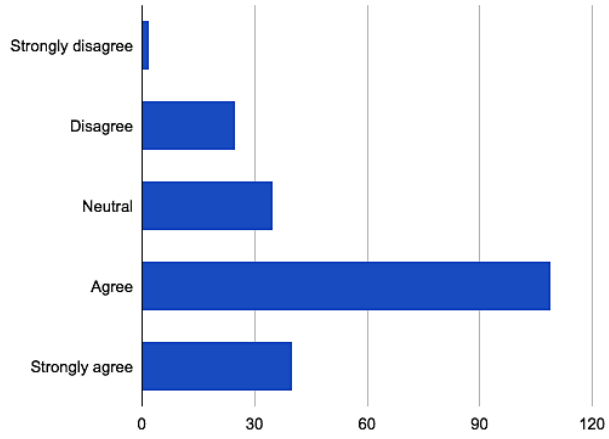


Table 4.5 Item 5: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 5	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	2	25	35	108	40	210
%	1.0	11.9	16.7	51.4	19.0	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	210	4	3.76	0.93		
	Summary statistics for medical and surgical doctors (n=206)					
	Number	Median	Mean	SD		
Medical	119	4	3.64	0.95		
Surgical	87	4	3.95	0.85		
	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	116	4	3.75	0.91		
Male	75	4	3.75	0.93		
	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	4	3.77	0.86		
Senior	107	4	3.76	1.00		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

Compared with disclosing all medical errors, fewer doctors believed that even potentially harmful medical errors should be disclosed to patients (70.4%). 12.9% did not agree. Very similar summary statistics were seen throughout the stratified levels.

Item 6

Only medical errors which cannot be hidden should be explained to patients

Figure 4.6 Levels of agreement with item 6 (numbers of responses)

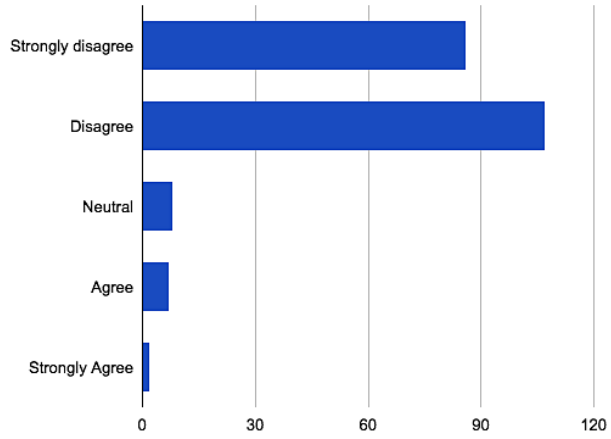


Table 4.6 Item 6: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 6	Answers for whole group (n=209)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	86	106	8	7	2	209
%	41.1	50.8	3.8	3.3	1.0	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	209	2	1.73	0.79		
	Summary statistics for medical and surgical doctors (n=205)					
	Number	Median	Mean	SD		
Medical	118	2	1.75	0.77		
Surgical	87	2	1.70	0.84		
	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	115	2	1.70	0.66		
Male	76	2	1.79	0.98		

	Summary statistics for junior and senior doctors (n=206)					
	Number	Median	Mean	SD		
Junior	101	2	1.78	0.87		
Senior	105	2	1.69	0.71		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 2 = Disagree

There was very strong disagreement with this statement - 91.8% total disagreement with 41.1% strongly disagreeing. With means showing more disagreement for surgical, male seniors but only by a small amount and the medians were all the same for the strata.

Item 7

Medical errors made by the practitioner should be discussed with the patient in terms she/he can understand

Figure 4.7 Levels of agreement with item 7 (numbers of responses)

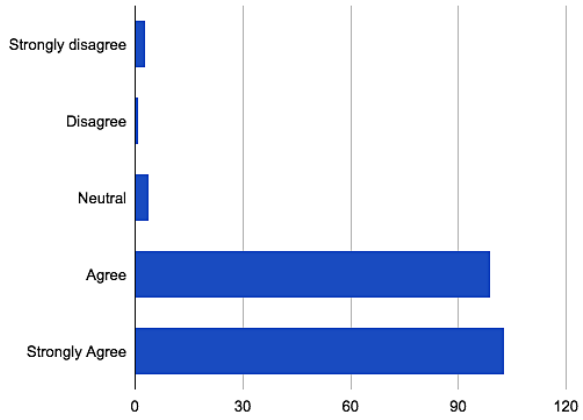


Table 4.7 Item 7: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 7	Answers for whole group (n=209)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	3	1	4	98	103	209
%	1.4	0.5	1.9	46.9	49.3	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	209	4	4.41	0.72		
	Summary statistics for medical and surgical doctors (n=205)					
	Number	Median	Mean	SD		
Medical	118	4	4.45	0.64		
Surgical	87	4	4.35	0.82		
	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	116	4	4.38	0.77		
Male	74	**5**	4.43	0.68	p= = 0.6275*	
	Summary statistics for junior and senior doctors (n=206)					
	Number	Median	Mean	SD		
Junior	101	4	4.44	0.66		
Senior	105	4	4.38	0.78		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

A median of 5 = Strongly agree

* = t test with equal variances

There was almost unanimous agreement with 96.2% total agreement and 49.3% felt strongly that this was true. The medians showed agreement

mostly, but when stratified for gender, males showed a median of 5, which indicates strong agreement. The mean between this and female gender was not significantly different, however, and can be seen to be similar to the mean difference in juniors and seniors where seniors had a higher level of agreement than juniors.

Item 8

It is best to try not to mention non-harmful errors

Figure 4.8 Levels of agreement with item 8 (numbers of responses)

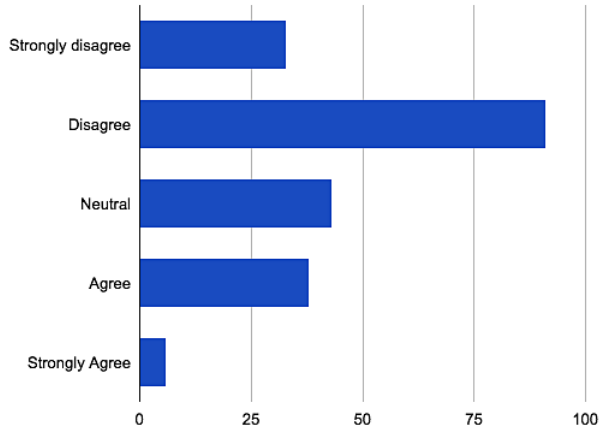


Table 4.8 Item 8: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 8	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	33	90	43	38	6	210
%	15.7	42.8	20.5	18.1	2.9	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	210	2	2.51	1.06		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	2	2.53	1.07		
Surgical	88	2	2.5	1.06		

	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	115	2	2.55	1.00		
Male	76	2	2.54	1.15		
	Summary statistics for junior and senior doctors (n=207)					
	Number	Median	Mean	SD		
Junior	101	2	2.57	1.04		
Senior	106	2	2.46	1.08	p = 0.4489*	

Note:
S disagree is Strongly disagree, S agree is Strongly agree

Median of 2 = Disagree

* = t test with equal variances

Although most disagreed (58.6%), there 21% who agreed and favored non-disclosure or non-transparency. The responses were similar for age, sex and specialty but there was a small effect for seniority where juniors were slightly more likely to agree (23.8%) to hide non-harmful errors than the more experienced doctors (19.8%). The medians for the stratified levels were 2 (disagree), which was the same as the whole group mean and there was no significant difference between the means for juniors and seniors.

Logistic regression was done for agreement to see whether junior/senior was a predictor for non-transparency. The regression models were not significant and medical/surgical group, gender and seniority were not shown as significant independent variables.

Item 9

The first stage of defending against possible litigation is not disclosing medical errors

Figure 4.9 Levels of agreement with item 9 (numbers of responses)

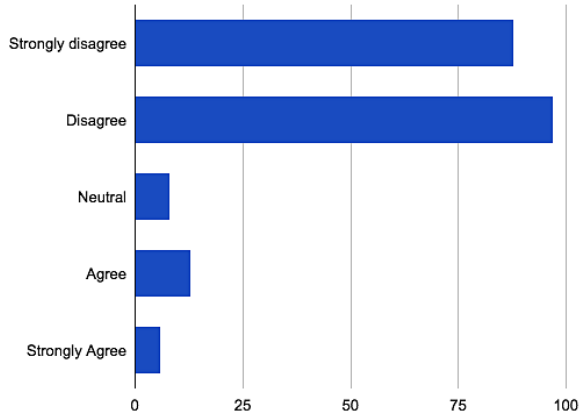


Table 4.9 Item 9: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 9	Answers for whole group (n=211)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	88	96	8	13	6	211
%	41.7	45.5	3.8	6.2	2.8	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	2	1.80	0.97		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	2	1.83	0.98		
Surgical	88	2	1.86	0.97		
	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	2	1.81	0.88		
Male	76	2	1.91	1.10		

	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	2	1.83	0.96		
Senior	107	2	1.85	0.99		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 2 = Disagree

There was consensus on the issue favoring disclosure (87.2%) rather than non-transparency where only 9.0 % favored non-disclosure.

Item 10

If the patient seems likely to initiate legal action, it is best to preempt this by disclosing the truth to the patient about the medical error

Figure 4.10 Levels of agreement with item 10 (numbers of responses)

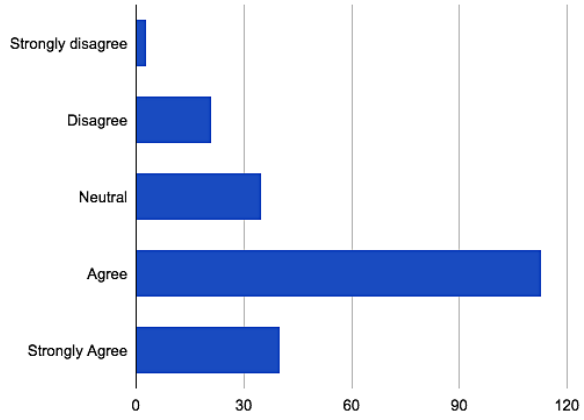


Table 4.10 Item 10: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 10	Answers for whole group (n=211)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	3	21	35	113	39	211
%	1.4	10.0	16.6	53.5	18.5	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	4	3.77	0.92		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	4	3.71	0.95		
Surgical	88	4	3.82	0.88		
	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	4	3.80	0.88		
Male	76	4	3.74	1.00		
	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	4	3.80	0.88		
Senior	107	4	3.72	0.96		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

Agreement was by 72% but a small percentage (11.4%) disagreed. Possibly meaning that this late disclosure of an error may not help to prevent litigation. The small percentage disagreement might also suggest doctors are concerned about medico-legal litigation but strike a balance in what they tell patients, so do not invariably disclose.This question promotes transparency

but implies that the person might not disclose unless medico-legal action may result - so only partially supporting total transparency. It also implies that doctors do not tell everyone about everything all the time but most do support transparency.

Item 11

After discussing a medical error made with a patient, an apology to the patient may prevent medico-legal sequel

Figure 4.11 Levels of agreement with item 11 (numbers of responses)

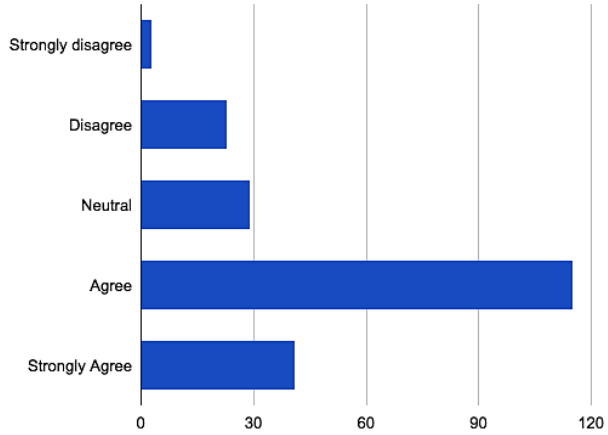


Table 4.11 Item 11: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 11	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	3	23	29	115	40	210
%	1.4	11.0	13.8	54.8	19.0	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	210	4	3.79	0.93		
	Summary statistics for medical and surgical doctors (n=206)					
	Number	Median	Mean	SD		
Medical	119	4	3.82	0.94		
Surgical	87	4	3.72	0.91		

	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	116	4	3.83	0.95		
Male	76	4	3.68	0.90		
	Summary statistics for junior and senior doctors (n=207)					
	Number	Median	Mean	SD		
Junior	101	4	3.69	1.01		
Senior	106	4	3.87	0.84		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

Apologizing was considered useful and acceptable and possibly advisable to prevent medico-legal repercussions by 73.8% of respondents. Again a small percentage of 12.4% disagreed. The medians were consistently at the 'agree' level and the means showed little fluctuations in the strata.

Item 12

It is ethically correct for a doctor to tell patients when she/he has made a medical error

Figure 4.12 Levels of agreement with item 12 (numbers of responses)

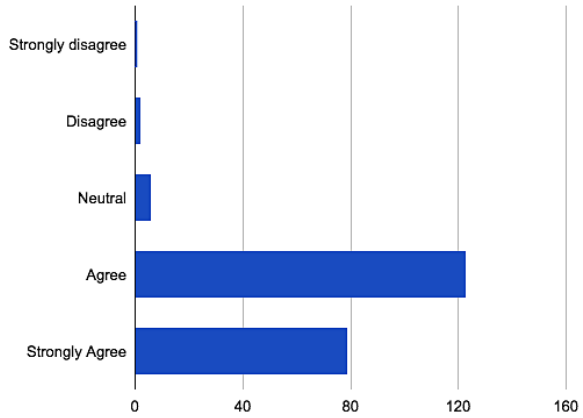


Table 4.12 Item 12: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 12	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	1	2	6	123	78	210
%	0.5	1.0	2.9	58.5	37.1	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	210	4	4.31	0.62		
	Summary statistics for medical and surgical doctors (n=206)					
	Number	Median	Mean	SD		
Medical	119	4	4.32	0.60		
Surgical	87	4	4.29	0.66		
	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	115	4	4.34	0.62		
Male	76	4	4.30	0.61		
	Summary statistics for junior and senior doctors (n=207)					
	Number	Median	Mean	SD		
Junior	101	4	4.32	0.62		
Senior	106	4	4.30	0.64		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

The ethical obligation of doctors to disclose medical errors to patients was well appreciated and understood among responders with 95.7% of responders showing agreement. There was strong agreement in 37.1%.

Item 13

Provision of training on the best way to disclose medical errors would contribute to more transparency with patients

Figure 4.13 Levels of agreement with item 13 (numbers of responses)

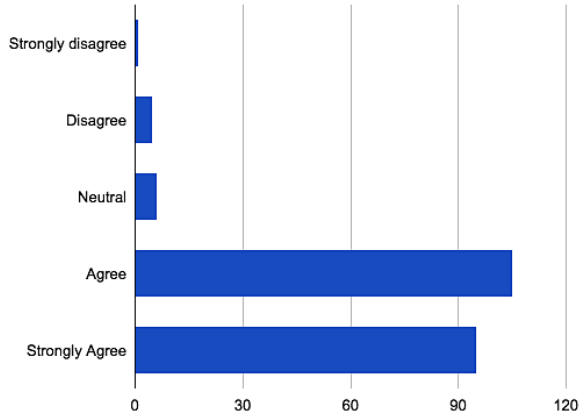


Table 4.13 Item 13: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 13	Answers for whole group (n=211)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	1	5	6	104	95	211
%	0.5	2.4	2.8	49.3	45.0	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	4	4.36	0.70		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	4	4.42	0.67		
Surgical	88	4	4.25	0.73		
	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	4	4.43	0.65		
Male	76	4	4.22	0.79		

	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	4	4.37	0.64		
Senior	107	4	4.34	0.75		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

There was general agreement on the need for training from 94.3 % that training would assist better disclosure. One of the barriers to disclosure of medical errors was lack of knowledge of the safest and correct way and a consistent approach to disclosure might also be employed.

Item 14

Possible victimisation is a concern if a practitioner was to tell colleagues about their own medical errors

Figure 4.14 Levels of agreement with item 14 (numbers of responses)

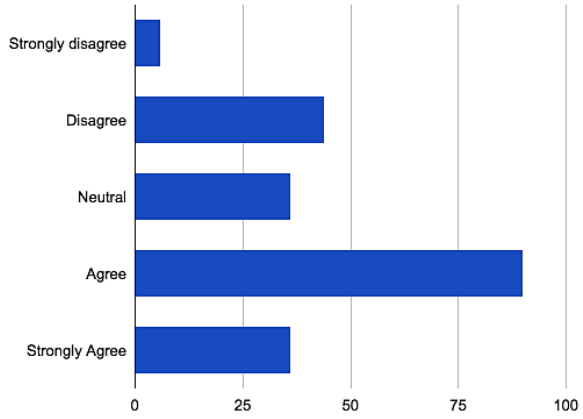


Table 4.14 Item 14: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 14	Answers for whole group (n=211)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	6	44	36	89	36	211
%	2.8	20.9	17.1	42.1	17.1	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	4	3.51	1.09		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	4	3.61	1.11		
Surgical	88	**3.5**	3.35	1.08	p= 0.1026*	
	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	4	3.66	1.07		
Male	76	4	3.33	1.11		
	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	4	3.76	1.03		
Senior	107	**3**	3.24	1.21	p = 0.0005*	

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

* = t test for equal variance

There was a bimodal response to this question - while most agreed that victimization by colleagues might deter them from disclosure (59.3%) there was still 23.7% who disagreed that victimization was a concern. This was examined further to try to establish who was less in agreement.

The medians were different for surgeons and seniors where the lower median suggests less agreement that victimization is a barrier. Univariate analysis using the variable showing a binary outcome of 'agree' or 'disagree' showed that the proportion of surgeons (35.3%) who disagreed was not significantly different from that of physicians who disagreed (25.0%). For junior/senior doctors the median had dropped to 3 for seniors. The 38.4% of seniors who did not consider victimization a barrier was significantly more than the 19.5% of juniors (p=0.006, Pearson chi square test of proportions). Testing the means between juniors and seniors, the mean of 3.76 for juniors was significantly more than the 3.24 for seniors (p= 0.0005, t test for equal variance). The difference in means between medical and surgical specialties was not significant (p= 0.1026) although the median was lower for surgeons.

Logistic regression: This relationship was further tested for the variable 'agree with the statement' and regression with junior/senior confirms an overall significant model (p=0.006) with seniors less likely to agree (p=0.007, OR 0.39, CI 0.20-0.77) In a different model, controlling for gender still gives a significant overall model (p=0.03) and is nearly significant for seniority (p=0.064, OR=0.51 CI 0.24-1.04)) but not for gender which was not significant (p=0.143, OR=0.58 CI 0.28-1.20). Tested with only gender and specialty neither was a significant predictor for agreement. It was the level of experience that was a significant predictor. Age and age group were also not significant as predictors.

Item 15

If a practitioner admitted an error to a patient it could invite medico-legal proceedings against them

Figure 4.15 Levels of agreement with item 15 (numbers of responses)

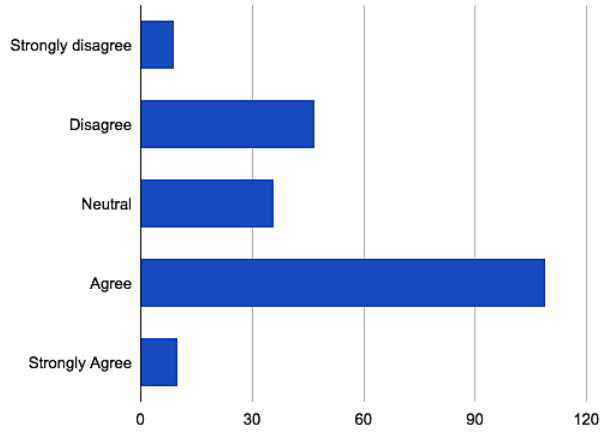


Table 4.15 Item 15: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 15	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	9	47	36	108	10	210
%	4.3	22.4	17.1	51.4	4.8	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	210	4	3.30	1.01		
	Summary statistics for medical and surgical doctors (n=206)					
	Number	Median	Mean	SD		
Medical	119	4	3.33	0.97		
Surgical	87	4	3.22	1.07		
	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	116	4	3.35	0.97		
Male	75	**3**	3.28	1.01	p= 0.7172*	

	Summary statistics for junior and senior doctors (n=207)					
	Number	Median	Mean	SD		
Junior	101	4	3.43	0.99		
Senior	106	**3**	3.15	1.01	p = 0.0502*	

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

* = t test for equal variance

Again a there was a bimodal response with 56.2% - just over half - agreeing that there were medicolegal risks from disclosure while 26.7% did not agree that medicolegal threat might present a barrier to disclosure.
The median was 4 for juniors and 3 for seniors indicating that those with less experience agreed that medico-legal threat was a concern if disclosure was made. The seniors were less concerned and the mean for juniors was borderline significant higher than that of seniors (p= 0.0502). The median for males was also lower but the difference in means was not significant (p= 0.7172).

Logistic regression - This relationship was further tested for the variable 'agree with the statement' and regression with junior/senior confirms an overall significant model (p=0.006) with seniors less likely to agree (p=0.066, OR 0.55, CI 0.29-1.04) In a different model, controlling for gender then demonstrates that gender is a confounder and seniority then becomes not significant (p=0.329) in a non-significant model (p=0.4567). Gender is also not significant in this model. If specialty is added to the model, it is not significant and neither are seniority or gender.

The reason for the confounding can be seen to be a high proportion of females in the juniors (70.6%%) compared with 29.4% who were male. This difference in proportions was significant (p = 0.006, Pearson Chi square test).

Item 16

Senior doctors tell junior doctors not to discuss medical errors with patients

Figure 4.16 Levels of agreement with item 16 (numbers of responses)

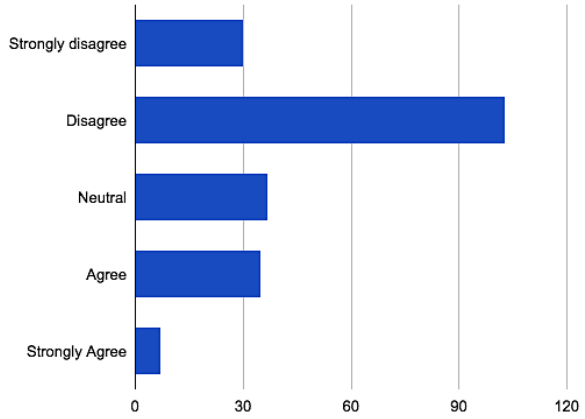


Table 4.16 Item 16: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 16	Answers for whole group (n=211)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	30	103	37	34	7	211
%	14.2	48.9	17.5	16.1	3.3	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	2	2.47	1.03		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	2	2.54	1.09		
Surgical	88	2	2.42	0.98		
	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	2	2.42	1.01		
Male	76	2	2.42	1.04		

	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	2	2.46	0.98		
Senior	107	2	2.50	1.09		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

* = t test for equal variance

Disagree was the response by 63% but there still was agreement about the behavior of seniors by 19.4%. There was no association of significance between those who agreed in terms of specialty, gender or seniority.

Item 17

Practioners sometimes make errors because of staff shortages and/or patient overload

Figure 4.17 Levels of agreement with item 17 (numbers of responses)

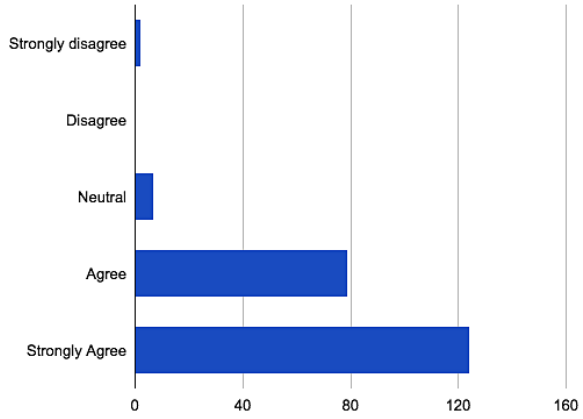


Table 4.17 Item 17: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 17	Answers for whole group (n=211)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	2	0	7	79	123	211
%	0.9	0	3.3	37.4	58.4	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	5	4.51	0.68		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	5	4.62	0.52		
Surgical	88	**4.5**	4.36	0.82	**p=0.01**,** p=0.094***	
	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	5	4.63	0.52		
Male	76	**4**	4.36	0.78	**p=0.008**,** p=0.63***	
	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	5	4.61	0.62		
Senior	107	5	4.41	0.71		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree, 5 = Strongly agree

* = t test for equal variance

** = t test for equal variance

*** = Pearson chisquare test

There was very strong agreement (95.7%) about the issue of staff shortages and patient overload with the median for the group being 5 (strongly agree). Only 0.9% (two responders) indicated that they strongly disagreed.

Stratifying for specialty, gender and seniority, the median for surgical disciplines was less at 4.5 and that for males was 4 (agree). This was due to a greater percentage of surgeons and males being neutral and fewer strongly agreeing than medical discipline responders and female doctors. The difference in means was significant between medical and surgical specialties and gender. The chi square test for a tabulation of specialty was near significance in both stratified levels.

Item 18

Sometimes medical errors are made because the hospital record system is inadequate

Figure 4.18 Levels of agreement with item 18 (numbers of responses)

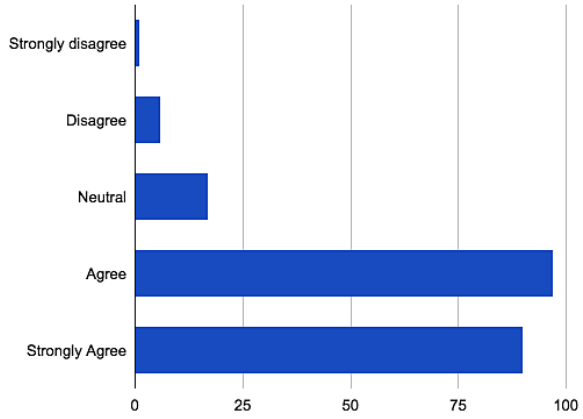


Table 4.18 Item 18: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 18	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	1	6	17	96	90	210
%	0.5	2.9	8.1	45.6	42.9	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	210	4	4.28	0.77		
	Summary statistics for medical and surgical doctors (n=206)					
	Number	Median	Mean	SD		
Medical	118	4	4.29	0.80		
Surgical	88	4	4.27	0.74		
	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	115	4	4.33	0.52		
Male	76	4	4.24	0.71		
	Summary statistics for junior and senior doctors (n=207)					
	Number	Median	Mean	SD		
Junior	100	4	4.31	0.78		
Senior	107	4	4.23	0.76		

Note:

S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

Hospital record system were seen as problematic by almost all doctors and results in errors, with 88.6% agreeing to this with a mode of 4. The various stratifications show there was overall consensus on the issue with no differences within the strata.

Item 19

Practitioners feel dishonest and/or guilty after hiding a medical error

Figure 4.19 Levels of agreement with item 19 (numbers of responses)

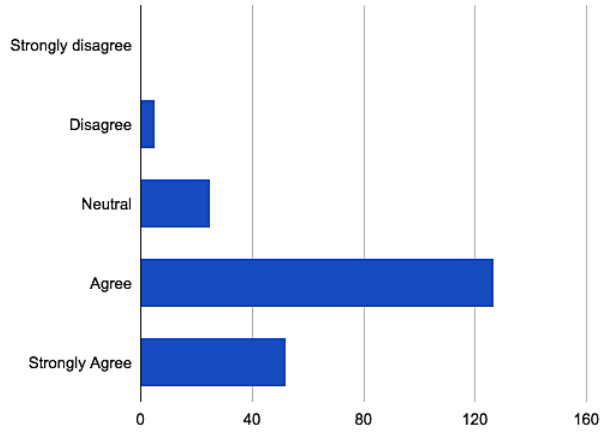


Table 4.19 Item 19: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 19	Answers for whole group (n=208)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	0	5	25	127	51	208
%	0.0	2.4	12.0	61.1	24.5	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	208	4	4.08	0.68		
	Summary statistics for medical and surgical doctors (n=205)					
	Number	Median	Mean	SD		
Medical	119	4	4.11	0.69		
Surgical	86	4	4.04	0.68		
	Summary statistics for female and male doctors (n=189)					
	Number	Median	Mean	SD		
Female	115	4	4.10	0.71		
Male	74	4	4.14	0.60		

	Summary statistics for junior and senior doctors (n=205)					
	Number	Median	Mean	SD		
Junior	100	4	4.11	0.69		
Senior	107	4	4.05	0.67		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

Doctors generally agree that hiding of errors causes conflict and guilt (85.6% agree). There were no differences in the stratifications for specialty, gender or seniority.

Item 20

Medical errors are handled internally in my Department

Figure 4.20 Levels of agreement with item 20 (numbers of responses)

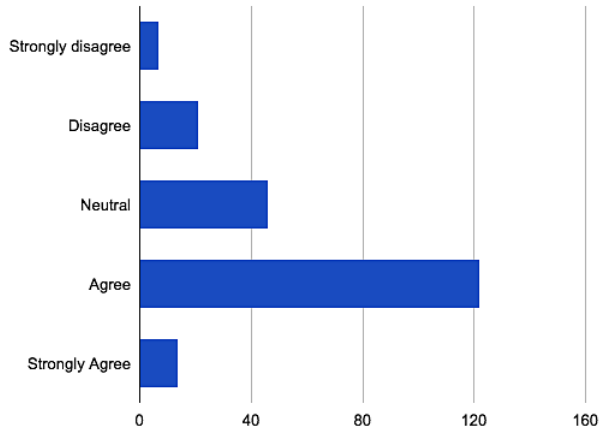


Table 4.20 Item 20: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 20	Answers for whole group (n=209)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	7	21	46	121	14	209
%	0.0	2.4	12.0	61.1	24.5	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	209	4	3.55	0.89		

	Summary statistics for medical and surgical doctors (n=205)					
	Number	Median	Mean	SD		
Medical	119	4	3.50	0.96		
Surgical	86	4	3.55	0.89		
	Summary statistics for female and male doctors (n=190)					
	Number	Median	Mean	SD		
Female	116	4	3.56	0.92		
Male	74	4	3.54	0.83		
	Summary statistics for junior and senior doctors (n=206)					
	Number	Median	Mean	SD		
Junior	101	4	3.53	0.94		
Senior	105	4	3.57	0.84		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

Agreement was 64.6% that internal systems were in place to notify errors and only 13.3% disagreed. The median at 4 for all stratifications indicated general agreement and there was no difference in responses for specialty, gender or seniority.

Item 21

Disclosing medical errors to some authority (your own Department, Hospital, Provincial Health or National Health authority) is essential to improve clinical practice safety

Figure 4.21 Levels of agreement with item 21 (numbers of responses)

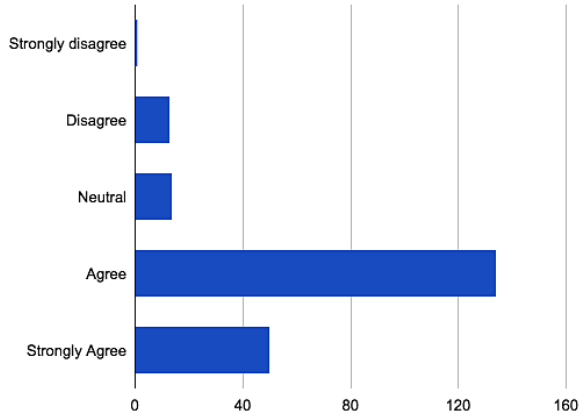


Table 4.21 Item 21 Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 21	Answers for whole group (n=211)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	1	13	14	133	50	211
%	0.5	6.2	6.6	63.0	23.7	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	4	4.03	0.77		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	4	4.08	0.70		
Surgical	88	4	3.96	0.86		
	Summary statistics for female and male doctors (n=192)					
	Number	Median	Mean	SD		
Female	116	4	4.07	0.77		
Male	76	4	3.98	0.80		

	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	4	3.96	0.79		
Senior	107	4	4.10	0.75		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

Notifying errors internally or to some external organization (perhaps in the hopes something can be improved) was thought to be important by 86.7% and there was little opposition to the idea with only 6.7% disagreeing. The median at 4 for all stratifications indicated general agreement and there was no difference in responses for specialty, gender or seniority.

Item 22

It is ethically correct for doctors to apologise to a patient if she/he has made a harmful medical error

Figure 4.22 Levels of agreement with item 22 (numbers of responses)

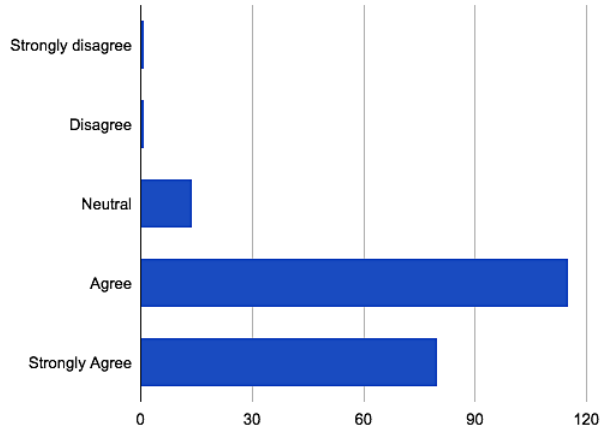


Table 4.22 Item 22: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 22	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	1	1	14	115	79	210
%	0.5	0.5	6.7	54.7	37.6	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	210	4	4.03	0.77		
	Summary statistics for medical and surgical doctors (n=206)					
	Number	Median	Mean	SD		
Medical	119	4	4.31	0.63		
Surgical	87	4	4.25	0.69		
	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	116	4	4.33	0.67		
Male	75	4	4.21	0.64		
	Summary statistics for junior and senior doctors (n=207)					
	Number	Median	Mean	SD		
Junior	101	4	4.30	0.63		
Senior	106	4	4.28	0.69		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

This is a critical question about what responders thought the correct ethical path was following a medical error. The responders agreed (92.4%) that the correct way forward was to apologize and only 1% disagreed. The median at 4 for all stratifications indicated general agreement and there was no difference in responses for specialty, gender or seniority. The means for male

surgeons was slightly lower indicating marginally less agreement than female physicians.

Item 23

Senior doctors should take the lead in disclosing medical errors

Figure 4.23 Levels of agreement with item 23 (numbers of responses)

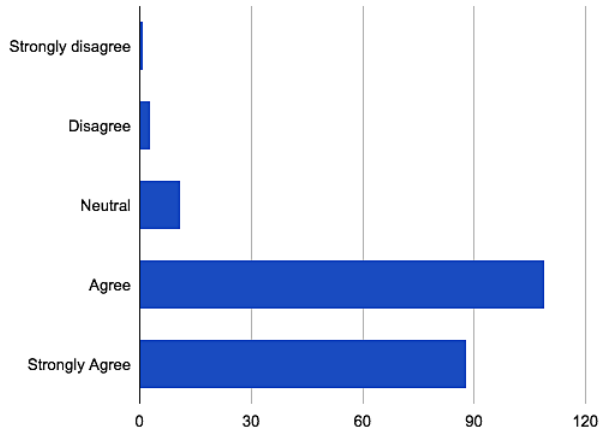


Table 4.23 Item 23: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 23	Answers for whole group (n=210)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	1	3	11	109	87	211
%	0.5	1.4	5.2	51.7	41.2	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	211	4	4.32	0.68		
	Summary statistics for medical and surgical doctors (n=207)					
	Number	Median	Mean	SD		
Medical	119	4	4.27	0.73		
Surgical	88	4	4.38	0.61		
	Summary statistics for female and male doctors (n=191)					
	Number	Median	Mean	SD		
Female	116	4	4.27	0.69		
Male	75	4	4.38	0.65		

	Summary statistics for junior and senior doctors (n=208)					
	Number	Median	Mean	SD		
Junior	101	4	4.27	0.68		
Senior	107	4	4.36	0.69		

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 4 = Agree

Agreement was 92.9% with the responsibility being with seniors, to lead the processes, as might be expected. The median was 4 (agree) throughout the strata. Surgeons, males and seniors had a higher mean for agreement but there was not statistically significant.

Item 24

Senior doctors encourage practitioners to tell patients about medical errors

Figure 4.24 Levels of agreement with item 24 (numbers of responses)

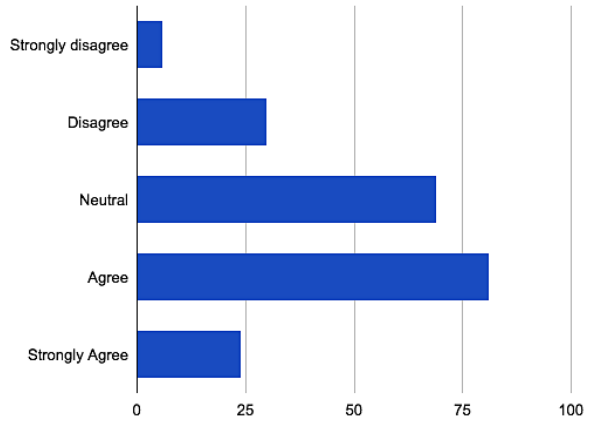


Table 4.24 Item 24: Answers for whole group and stratified for medical versus surgical doctors, gender and seniority with summary statistics.

Item 24	Answers for whole group (n=209)					
	S disagree	Disagree	Neutral	Agree	S agree	Total
Number	6	29	69	81	24	209
%	2.9	13.9	33.0	38.7	11.5	100.0
	Summary statistics for whole group					
	Number	Median	Mean	SD		
	209	4	3.42	0.96		
	Summary statistics for medical and surgical doctors (n=205)					
	Number	Median	Mean	SD		
Medical	118	4	3.42	1.03		
Surgical	87	**3**	3.43	0.88	p= 0.546***	
	Summary statistics for female and male doctors (n=190)					
	Number	Median	Mean	SD		
Female	115	**3**	3.44	0.92		
Male	75	4	3.39	1.03	p= 0.7365*,p= 0.470***	
	Summary statistics for junior and senior doctors (n=206)					
	Number	Median	Mean	SD		
Junior	101	**3**	3.36	0.95		
Senior	105	4	3.47	0.95	p= 0.4068*, p=0.889***	

Note:
S disagree is Strongly disagree, S agree is Strongly agree

A median of 3 = neutral, 4 = Agree

* = t test for equal variance

** = t test for equal variance

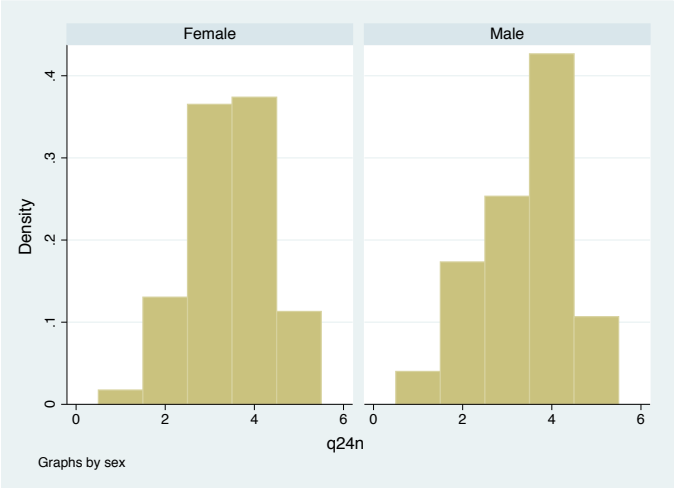
*** = Pearson chisquare test

In spite of almost all doctors (93% in item 23) believing that seniors should lead the process, only 50.3% agree or strongly agree that seniors actually

encourage disclosure. There was disagreement by 16.8% and 33% were undecided on the question. The median for the group overall was 4 (agree) but surgeons shows a lower median of 3 which is a neutral response. The mean responses for medical and surgical were almost identical. A similar lower median was seen for female gender although the mean was actually higher than males.

Looking at the numbers of responses, surgeons were more likely to give a neutral response compared with medical doctors but the differences were not significant (Pearson chi square p= 0.546). Gender showed a higher mean but lower median. This was due to 68.9% of the neutral responses being female and 58.3% of females showed agreement or strong agreement, which kept the mean high, but the median dropped to 3 (neutral).
The reason for the gender effect can be seen graphically by examining the histograms for the responses to the item by gender:

Figure 4.25 Histogram for item 24 (Senior doctors encourage practitioners to tell patients about medical errors) by gender



There were fewer responses of 'agree' for females than males but more 'neutral responses. This resulted in the higher mean with lower median.

For seniority, juniors had slightly more neutral responses (51.5%) and less agreement or strong agreement (45.6%) than seniors. This resulted in the

lower median and mean although not statistically significant. So seniors think they encourage disclosure but juniors are less certain about this.

Logistic regression for agreement was unable to show any independent associations and no significant findings were obtained.

4.3 Concluding comments

The results of this 'lay of the land' survey explored the knowledge of the SOCM doctors with respect to systems for medical error reporting methods in their departments. The ethical obligations to disclose errors to patients and also apologize for errors that had occurred during management were assessed. Other specific barriers such as victimization, the threat of medicolegal action and lack of leadership were probed. Whether training was required was also examined and whether there was any evidence that medical errors were being purposefully concealed. There were seven areas that might be viewed as barriers to disclosure and they are discussed as separate headings in the following chapter and compared with the normative expectations (gold standard) established in chapter 2.

Chapter 5 Discussion

5.1 Introduction

In this chapter the normative position as presented in chapter 2 will be contrasted with the responses from the SOCM survey (chapter 4). From this it can be understood how the SOCM clinicians are aligned with the desired normative standards. It might also inform a slightly modified ethical expectation from South African doctors, which allows for our situation within Africa and the limitations that doctors have in delivering medical care. This is based upon their actual responses to the questions or statements posed to them on various topics.

The chapter will begin by reviewing the response of the SOCM from chapter 3 and the response rate and how that might influence interpretation of the responses from the questionnaire. It will then examine the primary objective of the SOCM study, which was to establish the actual barriers to disclosure of medical errors. I will also contrast various strata such as physicians with surgeons, gender and seniority to show where different responses were obtained for those subgroups, which was a secondary objective.

Finally it will examine the conflicting prima facie obligations that the medical profession now face and consider solutions to the moral dilemma. Although the most obvious prima facie obligation is disclosure and transparency (see chapter 2), there is also an important and opposing obligation to protect the profession in order to continue to help patients. Pragmatism will need to prevail in finding the best and correct way forward in South Africa.

5.2 The SOCM (School of Clinical Medicine) study

To improve patient care and safety, it is necessary to have information about the causes of medical errors that occur within our public sector hospitals. System errors need to be addressed and improvements made and the information used to make patient care safer. It can be expected that clinicians

will assist in providing information of medical errors for corrective action to occur. The reason why this does not adequately happen is addressed in this research. This research reports new empirical data about barriers to disclosure that exist within the SOCM. The doctors invited to participate were working across the four academic teaching hospitals of the University of the Witwatersrand teaching circuit. The views expressed are those of public sector doctors although some doctors also have limited exposure to private hospitals. The responders were mostly South African born doctors (86%) so the study reflects attitudes of local doctors (who fully appreciate local conditions and cultures) and some from other African countries (9%) but very few were from outside Africa.

In the SOCM study responders there was a statistically significant under-representation of males in responders compared with the whole SOCM. Only 36% of responders were male whereas the SOCM was composed of 49% males ($p=0.0005$). This may create gender confounding in the analysis of the results of the survey. The mean age of the responders (41 years) was not significantly different from the clinicians in the SOCM (40 years). Response rates were significantly higher for surgical disciplines than medical (16% in surgeons versus 12% in the medical group, $p=0.0148$). Age of responders was not used to establish seniority, as it did not necessarily reflect work experience. Instead, a binary variable (juniors or seniors) was created and 'junior' doctors were defined as those who graduated as medical doctors in 2005 or later. Those who graduated prior to 2005 had more than ten years of work experience and were defined as 'senior'. There were 101 juniors (49%) and 107 seniors (208 of 211 responders gave year of graduation for this calculation of seniority). In considering results from the survey the whole group of responders was examined and then results were stratified for specialty (medical or surgical), gender, and seniority (junior or senior). This was done, with logistic regression where indicated, to assess gender (and other) confounding.

Some of the demographics for the SOCM could be established and the extent to which the sample of 211 responders was representative of the School

could be fairly accurately established fairly accurately. Of the 1 945 clinicians in the SOCM, nearly 80% (1 546) were sent an invitation to participate. The coverage of the potential survey population was therefore good and an overall response rate of 13.7% was obtained.

The phenomenon of declining participation of clinicians in surveys has been examined in the literature. It is desirable to get a response rate of 60-75% to avoid non-response bias,[60,63] but this is difficult to achieve in large surveys done by email. A response rate in the thirty percent range is fairly common with email surveys to physicians.[64] A review of surveys by Kellerman et al.[62] showed a lower response rate for doctors but suggested this might not be as significant because "physicians as a group are more homogenous regarding knowledge, training, attitudes, and behavior than the general population". Evaluation of the non-responder group has been found to be essential even where response rate was over 80% because there can still be important differences in high response surveys.[61] It is known that email surveys of doctors produce a 10% lower response rate than postal or telephone surveys and survey fatigue has seen declining response rates in doctor surveys over the past decades.[66] Wiebe et al. investigated the low response rate in physicians and found it was largely due to 36% of the 542 doctors surveyed having a policy not to participate in any surveys.[60] This group of non-participators was found to be senior male doctors, similar to the group who had a low response rate in the SOCM study. The response rate in the survey by Wiebe et al. was only 14%.[60] Sensitive topics, lack of time in addition to survey burden have been cited as reasons for low response rates in physician surveys.[64] To deal with non-responders in surveys it is suggested that they be described as fully as possible,[60] as was done in the SOCM survey. This allowed inferences to be made about bias and confounding.

5.3 Barriers to disclosure of medical errors

Specific barriers to disclosure of medical errors and the correct ethical way forward in the SOCM, were probed with a Likert questionnaire sent by email (see appendix 1).

5.3.1 Knowledge of issues and procedures as a barrier

(Items 1,2,4,5,7,12,17,18,22)

The first thing examined was whether clinicians in the SOCM were agreed as to the processes that should be followed. Knowledge of what to notify and correct processes for error reporting is considered important.[42] As discussed previously (chapter 2) for disclosures of medical errors to patients (level 1) the expected norms are well defined in the medical profession and there should be no confusion about the obligations of doctors to disclose errors to patients. With level 1 as well as disclosures to other persons or structures (level 2) judgment needs to be applied in South Africa where legal protections are incomplete and this is discussed below in section 5.5. The precise language used during a disclosure or an apology is important and admissions of personal guilt should be avoided. In the SOCM study, doctors were found to be knowledgeable about what should be done to deal with medical errors as well as the ethics involved and generally agreed on the way forward.

'Doctors making medical errors' was agreed to be a major problem in healthcare today by 54% of SOCM survey responders whereas 27% disagreed and 19% remained neutral. Instead, more doctors felt that hospitals were the problem with healthcare with 69% in agreement and only 15% disagreeing and 16% remaining neutral. In a study in Iran, over 90% of doctors felt medical errors were a "most important" problem in healthcare.[58]

In the SOCM study, staff shortages and an overload of patients in our public sector facilities were seen to be a cause for medical errors by 96% with 3% neutral and only 1% disagreeing. Medical specialists were significantly more

likely to 'strongly agree' with this than were surgeons (p=0.01, t test comparing means) while females were similarly more likely to 'strongly agree' (p=0.008). Hospital record-keeping systems were considered a cause of medical error by 89% with 8% being neutral and 3% disagreeing.

Regarding ethics knowledge and beliefs in the SOCM, the doctors were knowledgeable about ethical requirements for correct disclosure. Agreement was virtually unanimous (96%) that that there was an ethical obligation to disclose errors and almost half of these had been in 'strong agreement'. Only 1% disagreed while 3% remained neutral. Similarly, agreement was almost unanimous (96%) that disclosure should be in terms that the patient could understand with over half of these being in 'strong agreement'. This implies overcoming language barriers as well as reducing the technical level of the explanation to something that can be understood by a layperson. In keeping with Kantian ethical imperatives the vast majority of doctors believed that it was correct to disclose all harmful medical errors (83%) while 70% agreed that even potentially harmful medical errors should be notified.

Kaldjian et al. have shown that doctors are more likely to report major harmful errors (92%) compared with minor harm (73%) or no harm (43%).[42] They also showed that doctors might approve the reporting of medical errors but do not always understand the systems available to do it, indicating a possible breakdown in training. Doctors have also been uncertain "about the true causes of adverse event" and this may be used as a reason for not notifying.[42] Doctors decide on whether an error occurred and judge the harm or potential harm done to the patient.[77] The SOCM doctors showed a 70% agreement that this means that potentially harmful (near miss) errors need to be notified. The expected daily events that occur in busy public sector hospitals might foreseeably result in an overwhelming volume of these incidents and this might be the rationale why 30% did not agree with that view. A utilitarian approach may be held by this 30% in the SOCM study to justify not disclosing potential medical errors whereas there was more support for disclosing harmful errors. Rowe has shown that although doctors

recognize the ethical need, in practice they may not disclose at least a third of errors.[5] The patient might also fail to disclose all relevant information, such as drug abuse, which might affect the treatment and result in complications so the doctor might not be in control of as many elements as they presume.[5] They might therefore disclose an error and apologize where they did not directly cause the problem. Research on medical error disclosure and best ways of disclosure is still incomplete.[56] To advise that all errors should be disclosed and apologies made may be similar to reaching a conclusion off an incomplete and imperfect evidence base.

There was also a common understanding in the SOCM about apologies for medical errors. There was agreement by (92%) that an apology to the patient was ethically required, a virtue ethics approach. Only 1% disagreed while 7% remained neutral. Patients have been shown to require an apology[13] but there is a difference between knowing this is required and actually apologizing when there might be serious medicolegal repercussions unless protections are in place. To some extent apologies by doctors have reduced litigation in the USA but some malpractice lawyers are actually more likely to sue doctors who have apologized, even if it is inadmissible, as it serves as a marker for an acknowledged error.[47] A focus group approach by Gallagher et al.[18] found that doctors put a "spin" on what they actually say to patients to covey the error in a less serious light. This means the doctors might think they have disclosed and apologized but it is a watered down version of explanation and apology. This can be unsatisfactory to both doctor and patient.

5.3.2 Systems for reporting medical errors

(Items - 3, 20, 21)

Inadequate systems were a barrier to disclosure because only 24% of SOCM clinicians felt there were easy reporting systems in their workplace while 66% disagreed and 10% were neutral. Further examination of the responses with logistic regression showed that older and senior doctors thought there were easy reporting systems. The older age groups reached significance in the age 65 years and older (p=0.01), when controlling for gender. In the age group 45-

54 years it was near statistical significance (p=0.086). This implied that the junior doctors either did not know what the systems were or did not think they were easy to use for some reason. Medical errors were mostly handled internally in Departments and this was agreed by 86% while only 2% disagreed while 12% remained neutral. It thus appeared that systems were in place but they were seemingly not easy to use. There was also considerable agreement on how essential notifying errors was to a higher level (level 2) in order to improve safety for patients. There was agreement by 87% with 7% disagreeing and 6% neutral on the issue. There were no gender differences on systems for notification.

In general, therefore, doctors believed the systems were necessary but there was some disagreement as to whether they were easy to use, with older more senior doctors thinking they were, and the younger doctors more inclined to disagree.

It was shown in 2009 that simple systems (such as a "seven pillar approach") that are easily understood can facilitate disclosure and increase transparency.[54] These might require adequate and appropriate properly trained staff to be sustainable. A clear understanding of systems and demonstrations of improved patient safety following doctor's notifying adverse events was considered essential for the system to work optimally.[42]
The idea of “good people working in bad systems” means we constantly need to work to streamline what we do and make it safer.[78] The ongoing systems check adopted by the DOH (South African Department of Health)[26] is aimed at this systematic improvement and it is unfortunate that provision has not been made for staff to perform some of this work as the existing staff already has a large administrative load.

5.3.3 Victimization

(Item 14)
The perceived threat of victimization was identified as an important barrier to disclosure of medical errors in the SOCM. While 59% were in agreement that

it was a problem, 24% disagreed while 17% were neutral. When stratified, the median for surgeons was lower than medical specialties indicating less agreement (median 3.5 instead of 4) but the means were not significantly different. There were no obvious gender differences but seniors were less likely (median of 3) to agree than juniors (median of 4) and this was statistically significant (mean was lower; p=0005). To explore the relationship further, a logistic regression for agreement was performed. It was only significant for seniority (seniors were less likely to agree, p= 0.006) although after controlling for gender this decreased in significance to p=0.064. It thus appeared that level of experience was a factor with the junior, less-experienced doctors feeling more victimization than seniors. Gender can be seen to be a confounder due to the excess of females in the sample.

It was shown by Tagaddosinejad et al. in Iran that 76% of doctors supported disclosing errors to the hospital authorities but only 50% of doctors supported disclosure to their colleagues, fearing victimization.[58] Confidentiality has been suggested as a way of improving response rates[11] and reducing victimization. Ideally, this might be the answer, but the reality is that within a unit or department significant adverse events are usually well known, as several doctors might be involved in solving them. The fear of repercussions and "punishment" prevented notification of medial errors in 43% in a study done in Saudi Arabia.[11] "Whistleblowers" may be subject to being ostracized and "even forced to leave their institutions".[79] Shame, humiliation, loss of privileges, harsh reactions from patients and even loss of practice license are feared sequelae should doctors disclose an error.[57] Doctors might be reluctant to disclose errors to colleagues, fearing reprisals.[57] Half of doctors feared that the reporting system for errors would be used to implicate other people and 40% feared they might be identified even if it was an anonymous reporting system.[7] In Saudi Arabia where protection of doctors to enable disclosure was found to be desirable to improve patient safety, but cannot be guaranteed because of the country's laws, expatriate doctors may face deportation.[69]

5.3.4 Medicolegal threat

(Item 11 and 15)

The threat of medicolegal sequel appeared as a barrier to disclosure of medical errors with 56% agreeing about this risk while 27% did not. The overall median was 4 and remained that for juniors but it was reduced to 3 for seniors. Univariate analysis showed less agreement for males and seniors but this was only close to statistically significant for seniors (p= 0.0502). The lack of uniformity of answers created a bimodal response, which was further investigated by logistic regression. Seniors were less likely to agree (p= 0.066) than juniors but this reduced to insignificant levels after controlling for gender (p= 0.329) showing the confounder effect of the female excess. Female junior doctors showed more agreement with concern for medicolegal sequel to disclosure of errors. The reason for the confounding was a high proportion of females in the juniors (70.6%) compared with 29.4% who were male.This difference in gender proportions was significant (p = 0.006, Pearson Chi square test).

Medico-legal exposure by the disclosure of errors was not the major concern of SOCM clinicians and it might be speculated why this might be so. Senior doctors probably understand that they are practicing safely and encouraging safety in the junior staff so they do not make many errors. The errors that occur in patient care may be hospital errors and patients might understand the many shortages and malfunctions in public sector hospitals. Being employees, many also recognize the vicarious liability of their employer and all carry insurance against malpractice lawsuits. Central hospitals are mostly referral hospitals and the cases treated might already have an existing medical error from inadequate treatment at a peripheral hospital.

The medico-legal environment is known to be an important deterring factor to doctors' disclosure and even participation in apology strategies.[3,46,47,56,69] In the SOCM survey, the use of apology as a means to prevent medico-legal sequel to error was agreed by 73.8% of respondents. Only 12.4% disagreed that it would be helpful.

5.3.5 Lack of training in error disclosure

(Items 13, 19)

SOCM doctors were not sufficiently trained or guided on the safest and correct processes for disclosure of medical errors and how best to apologize. Almost all respondents (94%) agreed that training would benefit them and create more transparency while only 3% disagreed and 3% were neutral. Consistency in how disclosure and apologies are done could also be important. The other area requiring attention was possible support structures for doctors in an emotional way. Doctors may feel distress when they injure a patient, albeit unintentionally.[18] Persistent errors might lead to feelings of unworthiness and they may need to have adequate support structures to assist with this. Some clinicians have compulsive tendencies and although it may assist precision, it may also lead to them equating medical error with failure.[80,81] These feelings might be compounded when the error is hidden which results in further feelings of guilt and dishonesty. It may seem a no-win situation. Disclosure might lead to medico-legal prosecution or victimization by colleagues while non-disclosure may cause feelings of guilt and dishonesty. There was general agreement (86%) within our School that feelings of guilt and dishonesty resulted from hiding medical errors with 12% remaining neutral and 2% disagreeing. It might also not be their own error they are asked to hide but that of a colleague and the conflict surrounding this may be complex.

Part of efforts to “de-personalize” the occurrence of medical errors or serious event reporting was to try to develop a “no-blame” culture, where the emphasis was more on learning.[2] Proper training and other support have been recommended to enhance transparency.[57,58,81]

5.3.6 Actively hiding errors

(Items 6,8,9,10,16)

Cynical persons might have us believe that “doctors bury their mistakes”.[1] Some doctors have grown up with the admonishment "least said, soonest

mended". Against this background the mystique surrounding the medical profession has some reputation for protecting its own and not telling patients the truth. There are many reasons to hide errors including protection of work opportunity and avoiding punishment.[69] Alsafi et al. showed that doctors do not disclose errors because there was no incentive to do so, their reputation may be damaged, they felt some errors would never be discovered and they would avoid punishment.[11]

The SOCM doctors mostly did not agree with hiding medical errors. For non-harmful errors most (59%) disapproved of hiding errors but 21% agreed that they need not be mentioned, with 20% being neutral. There was a slight tendency for more non-disclosure for senior doctors but it was not statistically significant. Non-disclosure was not seen as a good way to defend against medico-legal action. Only 9% agreed that it was while 4% were neutral and 86% disagreed with the strategy. A recent online survey of over 7 500 doctors in 2016 shows a trend towards doctors hiding more errors. It showed only 78% believed that it is never acceptable to hide a harmful medical error and this is less than previous surveys in 2014 (91%) and 2010 (95%).[82] This was taken to indicate a trend toward rules being more subjective and situational rather than being absolute. This shows a tendency toward more doctors supporting act utilitarianism than deontological approaches.

Probing whether SOCM senior doctors tell juniors not to disclose produced a somewhat mixed response. Although 63% disagree about this, 19% agree that the seniors do tell the juniors not to disclose and 18% were neutral. Those who agreed had no particular characteristics and it was not only junior doctors. There might be some misunderstanding about this because juniors are very likely told not to discuss all of their complications and patient mismanagement on ward rounds in front of patients. This is not to hide errors but to disclose correctly, appropriately and sensitively to the patient in a confidential way. This advice might be construed as a directive not to disclose but it is more about appropriateness. Rather than hiding errors, 72% of the SOCM doctors agreed that it might be beneficial to disclose if a patient seems likely to initiate medical-legal proceedings. Only 11% disagreed while 17%

were neutral on the issue. There was a high level of disagreement that only medical errors that could not be hidden should be disclosed (92%) while 4% were neutral and 4% agreed. Doctors have previously been shown to regard error reporting as important but not actually do it well.[11,42] This discordance between beliefs and practice was not specifically explored in the SOCM study.

5.3.7 Lack of leadership as a barrier

(Items 23 and 24)

If disclosure is inadequate, surely senior doctors are failing to provide adequate leadership in the matter? Certainly SOCM doctors agreed that senior doctors should lead the processes for proper disclosure. This was agreed by 93% with only 2% disagreeing and 5% being neutral. Although the mean scores were higher (indicating higher level of agreement) for surgeons, males and seniors, the differences in means were not statistically significantly different. Whether leadership is adequate or provides a barrier to proper disclosure, depends on the desired outcome. Only 50% thought that seniors encourage disclosure of errors to patients while 17% did not think so and a big component was neutral responses (33%). The median scores were lower (towards neutral) for surgeons, females and juniors although these were not statistically significantly different. On logistic regression testing for the outcome variable 'agreement', there were no independent associations of significance. It would thus appear that seniors think they do encourage disclosure but juniors do not, but the effect was fairly weak. This might suggest that there are not clear policies led by seniors to disclose. Senior doctors are known to be role models for juniors and their behavior and practices have a strong influence on doctors in training centres.[42] Positive role-modeling has been significantly associated with positive attitudes to disclosure of medical errors but negative role-modeling may have even a greater effect.[12]

5.4 Summary of barriers to transparency: The current position

Transparency is the Holy Grail we seek as ethicists in South Africa and must be considered a prima facie obligation. This might require an evolution dependent on factors such as improvement to the legal framework, supportive hospital rules and cooperation of doctors and patients. According to Chamberlain et al. it is undisputed in the western world that disclosure of serious harmful events ought to be done and must be done.[52]

The barriers to disclosure of medical errors have been well studied and reported.[47,83] Perez et al. have reported the barriers to medical error disclosure as being "complex".[47] In a detailed review there were found to be four areas of inter-related factors; intrapersonal, which includes medical training, interpersonal, which included the camaraderie bond between health professionals as well as the bond between doctor and patient. The other two were institutional attitudes and societal norms and standards.[47] Perez,[83] a psychologist, has also highlighted the problem with the perfectionistic personalities and attitudes within the medical profession. Perfectionism was found to be a barrier to transparency and disclosure so actually prevents system improvements.[83] It needs to be openly discussed and dealt with to make progress. The actual barriers to disclosure might be similar in most studies but simple denial by doctors is probably an underlying factor in many cases of non-disclosure. As Couper has reminded us,[84] the processes following a medical error are like the grieving process with initial denial followed by anger, bargaining, depression and finally acceptance. The feelings of "remorse, guilt, inadequacy, and frustration" go against the doctor's intentions to help others and serve humanity in a meaningful way. Simply not seeing one's own errors or blaming others in a fit of anger may be the coping mechanism that enable some to continue medical practice.

The importance of protective legislation has been considered in Chapter two but was not specific studied in the SOCM survey. It has been said that "most physicians are much worse than judges or juries in distinguishing between

honest misjudgments and negligent errors, often confusing blameworthy deviation from acceptable professional standards and blameless misfortune or bad luck".[48] This casts into doubt a doctor's ability to use judgment when working in such close conditions with colleagues who might also be close friends. While camaraderie and support between doctors is vital (medicine is a team sport), we do need to identify unacceptable 'risk-taking behavior' in doctors and prevent patient injury. The recent document by the South African DoH addresses and discourages risk-taking behavior.[26] There are situations where mandatory error reporting has been introduced without protections. Such legislation was in place in two of three states in the USA in a survey regarding notification habits but protective legislation making such disclosure privileged was lacking.[42]

Utilitarianism, Deontology and Virtue ethics demand high standards from medical practitioners. We need to balance that with the demands of clinical practice in public sector medicine in South Africa and the perfectionistic attitudes of our clinicians and teachers. The SOCM study has shown that our clinicians fully understand that the ethical requirements favor transparency and disclosure of medical errors to patients and this must be done in terms the patient can understand. SOCM doctors supported that all harmful errors should be disclosed (83% agreement) and disclosure of potentially harmful errors was agreed by 70%. The disclosure of the 'near miss' errors can be useful in learning not to make the same error again, perhaps with a worse outcome, and can be as useful as disclosure of harmful errors. The value of disclosure of non-harmful errors to patients (level one) should be carefully evaluated as to its benefits versus the disadvantages for patient care and this might vary from patient to patient. There are arguments for disclosure and non-disclosure of medical errors that were presented in chapter 2 above.

SOCM doctors expressed the view that hospitals and hospital systems, presumably outside their control, were factors in the explosion of litigation in South African public sector hospitals. Hospital errors were thought to be more of a problem than practitioner errors and indicated that staff shortages and

poor hospital record keeping systems contributed to the medical errors. Only 24% viewed the systems for medical error reporting as 'easy' although errors were largely handled internally. Fears of victimization (59%) and medico-legal threat (56%) were found to be major barriers to notification. Training was seen as an essential provision for better transparency and it was acknowledged that seniors needed to show leadership. Even where total transparency has been advocated, the need for training in correct disclosure of medical errors and the addressing of concerns of victimization has been acknowledged for this to be possible.[57]

A gap has been described between the high moral position of medical doctors and their practice of actually notifying errors.[11,42,69] In spite of knowing the correct way to notify cases and knowing it is the right thing to do, doctors may not do it for a variety of different reasons. In a survey in Saudi Arabia, 61% had not actually reported a medical error in the previous year and only 54% agreed that medical error reporting had led to positive changes.[69] Unless the information is used for the intended purpose doctors might not comply with notification systems.

It was encouraging that there was little evidence in the SOCM study of active hiding of errors and most respondents disapproved of such a practice. Non-harmful errors were not viewed as seriously as harmful and disclosure was not unanimously agreed on for either. This is an almost common understanding by doctors. In an online survey in 2010 by the electronic journal 'Medscape' 10 000 responded to the question “Are there times when it's acceptable to cover up or avoid revealing a mistake if that mistake *would not* cause harm to the patient?[43] Only 60% answered 'no'. That is nearly half of doctors responding thought there were situations that required a tempered approach and life in clinical practice may not be as well defined as ethical principles. There is a moral and ethical obligation to disclose medical errors in terms of a duty toward patient autonomy and doctors are also ethically obliged to notify hospital and colleagues. There has been a swing toward transparency and disclosure for harmful medical errors with some positive

results.[56] Doctors were seen to endorse the principle and hospitals supported this which resulted in less medicolegal litigation.[57]

5.5 Prioritization of prima facie obligations and resolving conflicts

It might seem obvious once ethical theories have been presented and analyzed that the only way forward is to progress towards total transparency to the ultimate satisfaction of both patient and doctor. The prima facie obligation of doctors, as was argued in chapter 2, is toward disclosure of medical errors to patients and administrative systems for correction action. Apologies to patients should then be made. In South Africa there are conflicting obligations for the profession that in some instances mean there is an over-riding obligation, and this is protection of the medical profession against punitive medicolegal cases which threaten to cripple sectors of the public sector healthcare systems. Prima facie obligations might conflict and WD Ross suggests finding "the greatest balance of right over wrong".[50] Protection of the profession might, at times, assume a higher priority than total disclosure where adequate protections are not in place, as in South Africa.

Although we understand the enormous scope of injury from medical errors better today than twenty years ago we are still developing the systems required to reach total transparency. A utilitarian approach is required to protect both the doctor and the profession from the unbridled enthusiasm of those who would impose total transparency without regard for consequence and harmful damage. Without being overly dramatic, "the vision of government of achieving a long and healthy life for all South Africans" is currently threatened by an explosion of litigation.[26] There are problematic issues that have not even been fully discussed and have been glossed over in our rush toward correctness. This argument for not disclosing every detail to patients is similar to the one used for ethically supporting the use of triage in emergency departments around the world.[85] The triage ethical argument is underpinned by the fact that not all patients can be treated simultaneously

and in that situation it is acceptable to prioritize in the best possible way. It is largely based upon the utilitarian argument that when you have scarce resources you need to deploy them carefully and with insight and as long as this is done with transparency and justice, it is an ethically acceptable component of medical practice. Similarly with medical error reporting, if factors such as patient load and inadequate systems make it impossible to notify all medical errors and include near miss errors, then the more important harmful errors need to take priority.

Doctors hide their mistakes and this has been clearly shown.[3,82] Doctors are aware that learning new surgical techniques comes at a cost, causing themselves stress and patients injury. Damage to patients is seen with an increase in morbidity (patient injury) and death with 'learning curves' for most surgical procedures that represent progress in techniques. A learning curve might be 30-35 patients for a laparoscopic procedure for bowel cancer.[86] In South Africa, the brunt of the learning curves is born by the public sector hospital patients where training largely occurs. In spite of attempts to grow skills safely it is well reported in the literature that junior surgeons have a higher complication rate than experienced surgeons for most procedures. The extent of notification of all the errors that occur during training of new surgeons in a 'see one, do one, teach one' training environment is not known.[87] Although we might understand that "societal benefit" is an argument, it comes at a well-documented cost of increased complications.[87] We need medical progress and we need to teach new surgeons. No one is likely to dispute this, but patient safety is key and not always guaranteed. In spite of these reservations we feel transparency is ultimately good but it needs to be introduced slowly within a safe environment for doctors, as advances in medicine need to be made in a safe environment for patients.

In addition to a power element in doctor/patient relationships, there are genuine reasons why doctors do not disclose errors or apologize directly to patients. If these concerns could be addressed meaningfully, it would allow an increase in transparency, patient care and safety with a likely decrease in

medico-legal costs. These represent the 'barriers' to which this current research report is directed.

The recent 'directive' brochure from the Department of Health[26] would seem to negate any argument that doctors should not disclose medical errors, since error-reporting is “mandatory” by all healthcare personnel at public service hospitals and clinics. The errors to be reported include harmful and also "near miss" errors. However, there are no reassurances given to doctors or nursing staff that they will be protected, other than a vague idea of “anonymous reporting”. This seems improbable since the individual cases need discussion within hospitals so people involved in incidents are easily identifiable. In addition, names are on the reporting sheets. Anonymity is also only to be attempted unless there is a legal case about the incident.[26] As there is no provision made for specific staffing for this labor-intensive plan the load has been rather added to the 'sagging camel'. Meanwhile, the ethics of non-harmful errors still remains an ethical debate,[52] as such events are often undetectable by file review and are more dependent on voluntary disclosure. Knowing that such file review by hospital management staff may be used might also result in personnel writing less about incidents in files and effectively 'hiding errors' where this is possible. It is known that disclosure of 'non-harmful' errors remains more of a grey area and doctors are less likely to disclose these.[52] Only 44% of respondents in one study considered it necessary to notify ‘near miss’ errors.[58] In the aviation industry there is definite interest and value in 'near misses' as well as actual airplane crash incidents. In clinical medicine, unless there is a relevant new learning experience they often are disregarded for other higher priority issues. To some extent, it is about the judgment of the doctor with respect to autonomy of an individual patient and how the patient's best interests should be served. Sometimes the logic or ethical reasoning might be perfect but the conclusion is flawed. As stated by Leape, doctors may be responsible for patient care but not for "any errors that occur" during management. To conclude that doctors have absolute control over all events in hospitals is "absurd".[35]

There might be room for some judgment but the fiduciary relationship of doctor and patient needs to be protected at all times.[52] It might be argued that doctors working in public sector hospitals may be more likely to make correct judgments about disclosure of medical errors, as there are fewer financial incentives than in private sector medicine. On the other hand, in training environments, where inexperienced doctors are not adequately supervised, non-disclosure might occur more, as errors might be fairly common. The impact of junior doctors, in particular surgical training, as a cause of medical error and injury to patients has most likely been understated.[87]

There can be feelings of shame and guilt in making an error and damaging the bond the doctor has with the patient.[78] Fears of punishment due to litigation or victimization may encourage non-disclosure.[57,78] This makes the issue more complex as failure to disclose may enhance the guilt feelings. It would therefore be better to concentrate on adverse events (including some medical errors) where harm had occurred or there is an opportunity to learn from a 'near miss' than insisting on disclosure of minor non-harmful issues in our public sector working environment. Such insistence might serve to further erode patient confidence in our healthcare system, instead of promoting it. Issues that are 'relevant' to patient care should be our concern, not all the minor issues in and decisions in treatments given.[88] Doctors might also be concerned about media publicity should a mistake be reported in the media.[78] This is not an insignificant problem for doctors so unless reassurances about confidentiality are given, it is difficult to support notification of non-harmful errors.

Doctors alone are responsible for disclosure of their own errors. Medical students or nursing staff who observe medical errors probably do not have an ethical duty to inform the patient that an error has been made.[89] That is the duty (and prerogative) of the doctor in charge of the patient. Other doctors, nurses and students probably rather have an obligation to facilitate disclosure where it is not done. They may notify a higher authority where a private discussion with the doctor involved in the error is fruitless.[90] They should not directly approach the patient. The processes of disclosure of every event

particularly where several patients were involved but even of individual patient errors “could be resource-intensive and time-consuming”.[91] In our public sector we need to look at optimal staff usage and help more patients, not deploy staff to deal with numerous non-harmful 'near misses'. Although doctors might support an argument for their holding the power of discretion, patients might prefer and demand disclosure. It seems common courtesy for doctors to apologize to a patient where the patient has had a prolonged wait but for doctors to apologize for poor communication skills might be asking too much although these might be the expected norms elsewhere.[52] Even in a well-developed healthcare system as in Canada, the ability of the healthcare professionals to properly disclose every error to patients is very doubtful as the numbers of cases would be “staggering”.[3] Even if the success rate with all procedures done on patients is over 99% the number of adverse events is nearly two per day per patient in intensive care, given that almost 180 procedures per day are performed on the patients.[35]

Regarding apologies to patients: In Canada doctors were advised by their College of Physicians and Surgeons that “an expression of sorrow and regret may be appropriate and should not be taken as an admission of responsibility “ although Waite,[3] a lawyer, does not agree that such a disclaimer would be valid in court. He stated that "unless the Legislature enacts an apology privilege….true apologies in disclosure conversations will retain significant legal risks”. In South Africa, there are few protections and disclosures of error or apology to patients may be used in a court of law as an admission of guilt in order to prosecute a doctor for negligence.[92] The "second victim" in medical errors is often the doctor who makes the error.[93] The recent DoH document[26] mandating that doctors do something potentially harmful to themselves without legal protection is not likely to achieve the support it requires to achieve success. A survey by Harper et al[7] identified requirements for successful implementation of a medical reporting system. These requirements included "immunity from punishment and a guarantee that information reported would be used to make changes to the system". The WHO (World Health Organization) source document from which the DoH document originates was developed and improved by the WHO since 2004.[23] A vital and

essential component is the proper analysis and feedback of the notification data collected back to the health care workers who supplied it with actions to improve faulty areas and an increase in patient safety.[23] The end point of the process of data collection is improving patient safety and care and is not "learning" as has been implied.[26] Collection of medical error statistics in a safe way is only the beginning of a further process of investigation, communication, disclosure and apology, system improvement, data analysis and education and training.[5] System improvement must be prioritized for such a labour-intensive scheme to be supported by medical personnel and justified in terms of the effort. The ethics involved in disclosure is a two-way street - healthcare practitioners have an obligation to disclose and deal with medical errors, and healthcare systems need to protect workers from "unjustified denunciation and retaliation".[26] Neither doctors nor healthcare providers can act in isolation or without trust that includes a reliable track record, which is not yet a reality in South Africa.

5.6 Concluding comments

Bioethicists need to support protected disclosure of medical errors so that we can systematically improve hospital care and reduce errors. It is more than two decades since Leape stated "Only when errors are accepted as an inevitable, although manageable, part of everyday practice will it be possible for hospital personnel to shift from a punitive to a creative frame of mind that seeks out and identifies the underlying system failures".[35] Bearing in mind the problems and issues with full disclosure, including doctors concerns with medico-legal action and victimization, full disclosure in the South African context cannot be recommended at this stage. Given the sub-optimal environment for transparency doctors need to proceed with care. In making any written notes, doctors should be advised to show extreme caution, as there is no legal protection should they either disclose errors or apologize for errors. In this environment, doctors might be better advised to deal with the more important medical errors and spend less time on trivial non-harmful situations that may occur fairly commonly. Doctors need to protect themselves

from litigation while honoring their obligations to patients and colleagues. We need to move away from punitive systems to improvement of systems and a 'no blame' system is the only way to do this but it may involve a process of slow evolution.[94]

This pull in seemingly opposite directions is nothing new to South African public sector doctors and not anything unique to South Africa. Our duty, as always, is to our patient and level 1 disclosure may always be a private conversation between doctor and patient but written statements need to be guarded. The doctors have indicated their need for training to become better at appropriately disclosing medical errors but should understand risk when doing so.

Chapter 6 Conclusions and recommendations

Doctors might be hard pressed by ethicists to disclose all facts relating to medical errors by ethicists and simultaneously discouraged from doing so by health insurers, their seniors or other interested parties. The correct resolution of these conflicting obligations should respect the ethical demands and requirements to protect the patient. Level 1 disclosure (doctor to patient) has a differing obligation to level 2 disclosures where some notification of a medical adverse event is made to an outside person, hospital or agency, such as the Department of Health.

Level 1 obligations must satisfy patient autonomy, an imperative dictated by deontological principles and which has strict obligations and requirements. The demand for full disclosure of harmful medical errors is irrefutable. For level 2 disclosures other considerations need to be carefully weighed up as privacy of patient information and legal safety for the doctor involved in reporting incidents must also be considered. Utilitarian arguments support a modified approach, as there are several conflicting issues and obligations. In both levels of disclosure the requirement is for transparency although the current environment is not supportive or favorable in many ways.

The major barriers to open transparency found in the SOCM study were: Fears of victimization (significantly more for juniors than seniors) and medicolegal prosecution, poorly understood or lacking systems for error reporting, and lack of training in the correct, best and safest way to disclose medical errors and make appropriate apologies. Strong leadership by senior doctors would be an important cornerstone for improvement and training might be needed to facilitate this. Emotional support should be offered to help doctors deal with the feelings and guilt they experience when medical errors occur and also when they are not disclosed adequately. These problems occurred against a backdrop of inadequate hospital support with staff shortages and inadequate hospital record systems.

There are some medium to long-term measures that may assist us in South Africa. Firstly, we must consider introducing a 'no-blame' or 'no-fault' environment as currently we have a punitive medico-legal system and the public sector has a hierarchical structure and attempts to use a top-down management style. In considering such a 'no-fault' system the costs (to Province or National health budgets) can be a deterrent.[3] Since doctors' major fear is of victimization, trust needs to be established between role players. The public health authorities need to work with medical staff to address the problem and entrench integrity in the processes. This includes the assurance that they are responsible for litigation incurred by staff. Senior doctors, in turn need to control staff that show negligent or risk-taking behavior.[26] Higher volumes of patients and surgery through the system will be difficult to accommodate as already there are indications that staff shortages and poor systems, including record keeping, are adversely influencing safety of patients. Patients who are carefully assessed might disclose important risk factors in their own health that make an adverse event more likely.[81] High volume, superficially assessed patients may not be given the chance to alert doctors. Safety may increase with high volume surgery but this has to be shown to be related to specific surgeon's expertise that improves with volume, not inexperienced junior doctors being taught.[95]

Secondly, it would be best to concentrate on large problems and major errors within our healthcare system before addressing the smaller errors. This is not to minimize the importance of potential errors (near misses) and their value as a learning experience to prevent future errors but the problem is overwhelming as it stands and we need to begin somewhere. Even relative purists[57] prefer to endorse prompt disclosure of 'significant medical errors' rather than all errors including near misses. Eroding the confidence of the public in our healthcare facilities should be avoided.[52] Cooperation of our medical colleagues is essential if the barriers to disclosure are going to be successfully addressed and overcome.

Thirdly we urgently require legislation in place to offer protection to doctors who wish to discuss errors in a candid way with patients and their families. Protection by developing new laws in the USA has increased disclosure and reduced litigation payouts but this legislation is not even uniform across first world countries like the the USA at present.[56] Now that we have support and direction from the National Health Department we require the amendments to legislation to make it safe.

Fourthly we need to carefully examine what we are teaching medical students as they progress towards being doctors. The development of “moral character” should be prioritized whereas it appears that students become less moral and more insensitive as they progress through training.[47] The problem might be the adjustment students need to make to being psychologically prepared for the sights and experiences of major trauma management and treating oncology patients who might be desperately ill. The effect on the developing psyche seems to be blunting of affect and denial rather than empathizing with patients when errors are made. The culture of perfectionism in medicine and training and the impact this has coping later on needs to be explored in ongoing research to develop training appropriately. We need to replace "the pursuit for perfectionism with the pursuit for excellence" and this needs to be done at a grassroots level and begin with medical student training.[83]

Transparency improves doctor-patient relationships where information is appropriate and in context. On the other hand, unnecessary offloading of insecurities by doctors might create insecurity in the relationship. Doctors are not supposed to appear weak and indecisive but on the other hand should never be seen to be concealing important issues. Care needs to be taken that 'non-harmful errors' do not later resurface as a problem that requires some explanation. When errors occur we might not initially have enough information to make correct judgments about whether significant harm has occurred and whether disclosure is appropriate. The actual cause of some medical events is complex and the causes might be multifactorial so limited and appropriate initial disclosure needs to be done carefully with this in mind.

In any situation, the past cannot be redone, so for each patient the way forward is of most importance, rather than trying to allocate specific blame. The value is in allowing growth in the system to prevent similar events to others, and providing safer patient care.

Specific Recommendations resulting from this research:

1) **Ethical recommendations for the HPCSA for medical errors or severe adverse events where harm has occurred to the patient or near miss errors.**
   a) In the event of a medical error or severe adverse event, the doctor in charge of the patient is required to provide all the facts necessary for the patient to understand what has occurred and be able to participate in decisions on further management.
   b) This requires full disclosure of the relevant facts to the patient, in terms she/he can understand.
   c) In events where no harm has occurred (a near miss event) the doctor should provide information as appropriate but the principle to be followed is that of open transparency.
   d) In reporting medical errors or adverse events to other persons, structures or higher levels of the healthcare system, appropriate attention to patient privacy and confidentiality should be ensured.

2) **Clear and easily understood systems** for notification of adverse events should be in place[54] and the recent system introduced by the Department of Health[26] sets the tone for such systems at lower levels in individual Departments.

3) **Safe interpersonal environments** must be created both to protect doctors from victimization and also from medico-legal threat so that disclosure may occur in a protected environment.

4) **Training** is required to instruct doctors on safe and correct ways to disclose medical errors and other adverse events and how to make

apologies to patients without exposing themselves to risk. The university could assist the public sector hospitals with this recommendation.

5) **Medical student education** needs to accommodate the increasing requirement for transparent and open communication with patients about their care and modifications might be required to the curriculum to allow this.

6) **Emotional support** for staff that has made a medical error needs to be provided to cope with the trauma resulting from such and event. Again the university could assist in providing this support.

7) **Correct legislation** to allow safe disclosure must be introduced to protect doctors and allow full disclosure, which can inform healthcare system changes to improve patient care.

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Appendix 1: Questionnaire items

Questionnaire Number …….

Please check or complete all items that apply:

Gender: Male Female

Age (years):

Country of birth South Africa Africa (other) Outside Africa

Specialty:

1. Medical (Includes General medicine and all medical disciplines and specialties, Psychiatry, Anesthetics, Pediatrics, Family medicine etc.)

2. Surgical (Includes General Surgery and all surgical disciplines and specialties, Obstetrics & Gynecology etc.)

Current position (Intern or community Service under Medical Officer):

Medical officer Registrar Consultant

Year of Medical Degree graduation:

A Five point Likert scale will be used for each

1= Strongly disagree, 2= Disagree, 3=Neutral, 4= Agree, 5=Strongly agree

Items or Statements

1. ‘Medical errors by doctors’ is one of the most important problems in health care.
2. ‘Medical errors resulting from hospital errors/faults’ is one of the most important problems in health care today.
3. There are easy to use systems for medical errors reporting in my workplace.
4. Doctors should disclose all harmful medical errors to patients.
5. Doctors should disclose all potentially harmful medical errors to

patients.

6. Only medical errors, which cannot be hidden, should be explained to patients.

7. All medical errors made by the practitioner should be discussed with the patient in terms she/he can understand.

8. It is best to try not to mention non-harmful errors.

9. The first stage of defending against litigation is not disclosing medical errors.

10. If the patient seems likely to initiate legal action, it is best to preempt this by disclosing the truth to the patient.

11. After discussing a medical error made with a patient, an apology to the patient may prevent medico-legal sequel.

12. It is ethically correct for a doctor to tell patients when she/he has made a medical error.

13. Provision of training on the best way to disclose medical errors would contribute to more transparency with patients.

14. Possible victimization is a concern if a practitioner was to tell colleagues about their own medical errors.

15. If a practitioner admitted an error to a patient it could invite medico-legal proceedings against them.

16. Senior doctors tell junior doctors not to discuss medical errors with patients.

17. Practitioners sometimes make errors because of staff shortages or patient overload.

18. Sometimes medical errors are made because the hospital record keeping is inadequate.

19. Practitioners feel dishonest and guilty after hiding a medical error.

20. Medical errors are handled internally in my Department.

21. Disclosing medical errors to some authority (your own Department, Hospital, Provincial Health or the National Health Authority) is essential to improve clinical practice safety.

22. It is ethically correct for doctors to apologize to a patient if she/he has made a harmful medical error.

23. Senior doctors should take the lead in disclosing medical errors.

24. Senior doctors encourage practitioners to tell patients about medical errors.

Appendix 2: Email to doctors and Information sheet

Dear Professor or Doctor, Please assist me in completing my research project toward a higher degree (MSc in Bioethics and Health Law). Your identity is protected and responses are anonymous.
The Information sheet is below and the link to the survey takes you to the questions which should only take about ten minutes. There is a small 'reset' option on the right of each question line if you wish to change an answer. Please answer all questions.
Many thanks for considering participation, the results will be sent to you once analyzed.

Kind regards,

Professor Trevor Carmichael
Head: Ophthalmology
Head: Department of Neurosciences
082-411-5211

Please follow this link to the online questionnaire and complete it as soon as possible:
http://j.mp/2bkxyz

Information sheet

Barriers to medical error reporting and disclosure by doctors: A bioethical evaluation

Dear Colleague,
My name is Trevor Carmichael and I am doing research toward an MSc (Bioethics & Health Law). My Supervisors are Prof. Ames Dhai and Dr Kevin Behrens who are senior Bioethicists in our Faculty. Prof. Dhai is Head of Department at the Steve Biko Centre for Bioethics at our University. I would like to invite you to participate in this questionnaire-based study.

My area of interest is how doctors who practice within South Africa perceive and handle medical errors within their work specialty. Medical errors in this questionnaire imply harmful medical errors, where the patient sustains some injury as a result of a medical mistake. This might vary from a prolonged hospital stay, admission to hospital for treatment or a serious irreversible harm or harm that might have placed the patient at risk for death. The issue is a sensitive one but I would ask you to respond as you see fit, as there is not necessarily any right answer to these issues in South Africa.

The questionnaire is completed online and your identity will be completely protected. You will be anonymous because there are no identifiers on the questionnaire and the researcher will not receive your email address. The survey will take about ten minutes to complete. Your specialty is requested because I am interested in whether the responses differ significantly between surgeons and physicians (non-operating).

You are under no obligation to participate and there are no risks or direct

benefits to you if you participate in the study. However, guidelines developed from this study could be of benefit to you and doctors in the future. The results of the research will be sent by email to all doctors in the participating Departments including those who indicate that would prefer not to participate. Guidelines for how we react to medical errors in the future will be developed based on the results. The research has been approved by the Human Research Ethics Committee (Medical) at the University of the Witwatersrand (Approval M 160516).

Thank you for considering this request and my contact details are below, should you wish to contact me directly.

Yours sincerely,

Trevor R Carmichael (Chair & Head of Ophthalmology)
Head: Department of Neurosciences
School of Clinical Medicine
Faculty of Health Sciences
University of the Witwatersrand

Phone (Office): 011-717-2549
Mobile: 082-411-5211

Trevor.Carmichael@wits.ac.za

For queries regarding the ethics of this study please contact Professor Cleaton-Jones, Chairman of the HREC at 011-717-2301.

(http://www.witshealth.co.za/pages/ethics.aspx

Appendix 3: Copy of Ethics approval form

R14/49 Prof Trevor Carmichael

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160516

NAME: (Principal Investigator)	Prof Trevor Carmichael
DEPARTMENT:	Steve Biko Centre for Bioethics Online Survey
PROJECT TITLE:	Barriers to Medical Error Reporting and Disclosure by Doctors: A Bioethical Evaluation
DATE CONSIDERED:	27/05/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Ames Dhai and Dr Kevin Behrens
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	05/08/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in May and will therefore be due in the month of May each year.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 4: Plagiarism declaration

DEPARTMENT OF NEUROSCIENCES

Neurology, Neurological Surgery, Ophthalmology, Otorhinolaryngology, Psychiatry

School of Clinical Medicine, Faculty of Health Sciences,
7 York Road, Johannesburg 2193, South Africa
Tel: +27 11 717-2774 · Fax: +27 11 717 2775

Plagiarism declaration for written work

I TREVOR CARMICHAEL as a postgraduate student registered for a MMed at the University of the Witwatersrand declare the following:

- I am aware that plagiarism is the use of someone else's work without their permission and or without acknowledging the original source.
- I am aware plagiarism is wrong.
- I confirm that this written work is my own work except where I have stated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or if I have failed to acknowledge the ideas or writing of others.

Signature .....

Date 7/1/17